DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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February 4, 2000

E. Edward Kavanaugh
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Washington, D.C. 20036-4702

Re: Over-the-Counter Drug Labeling (Docket No. 99P-4617/CP1)

Dear Mr. Kavanaugh:

This letter is in response to the petition submitted on October 22, 1999, on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA). The petition, submitted under 21 CFR 10.30, requests a two-year extension of time for compliance with the agency's recently published final rule on the labeling of over-the-counter (OTC) drug products. *See* 64 FR 13254 (Mar. 17, 1999). The final rule establishes a standardized format for presenting required drug labeling information. The rule is intended to assist consumers in reading and understanding OTC drug labeling, in selecting among various products, and in using these products safely and effectively.

The rule went into effect on May 16, 1999.[1] However, for the large majority of products, compliance with the final rule is not required until, at the earliest, May 16, 2001 (the "primary implementation date"). 64 FR at 13274. CTFA requests an extension of this date to May 16, 2003.

CTFA argues that the additional time is needed to resolve several outstanding issues, including "an appropriate small package exemption" and the need to "harmonize" the labeling of products that must meet both drug and cosmetic requirements. CTFA Petition ("Pet.") at 7-8. Many of the issues raised by CTFA were also raised in a petition submitted by the Consumer Healthcare Products Association (CHPA) on October 1, 1999 (Docket No. 98N-0337/CP2). Both petitions requested additional time to address the issues of trade dress, columns, single use and convenience packages, extended text labeling, small packages (including the issue of type size), and the submission of exemption requests under 21 CFR 201.66(e).

A two-year extension, according to CTFA, will allow the industry to continue its dialogue on these issues and ensure fair implementation of the final rule for cosmetic-drug products. The petition also states that this extension would not harm the public health.

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[1]On April 15, 1999 (64 FR 18571), the agency published a correction to the effective date of the final rule.

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Because the petitions substantially overlap, and seek essentially the same relief, the agency incorporates herein the response provided to CHPA. In this response, the agency will focus only on issues not raised in the CHPA petition: (1) whether a stay is needed to discuss a categorical small package exemption is needed; and (2) whether a stay is needed to discuss ways to "harmonize" the new "Drug Facts" labeling with existing cosmetic labeling.

The agency has carefully considered the petition, and all relevant information related to it. For the reasons discussed below, and for the reasons discussed in the response to the petition filed by CHPA (*see* attached), the agency is granting CTFA's petition in part and denying it in part. The agency, in an upcoming notice in the Federal Register, will publish notice of an amendment to the implementation plan extending the primary implementation date by one year, to May 16, 2002 (and the corresponding implementation date for low volume products to May 16, 2003).[2]

I. Analysis

Cosmetic-drug products, as CTFA acknowledges, must meet all applicable labeling requirements for both cosmetic products and drug products. CTFA believes, however, that the final rule on OTC drug labeling fails to recognize the additional labeling burden faced by cosmetic-drug products. Pet. at 2. CTFA also argues that the agency has no evidence with which to support the application of the new OTC labeling format to cosmetic-drug products and, in particular, to cosmetic-drug products that are sold without specific dosage limitations. The inherent safety of the latter category, according to CTFA, makes the use of new format an "unnecessary imposition." Pet. at 2-3. Nevertheless, CTFA states that its members will make a good faith effort to comply with the new rule, provided additional time is given to address several issues. Pet. at 3.

The two issues not fully addressed by the agency in its response to the CHPA petition are: (1) CTFA's request for a categorical small package exemption, and (2) CTFA's inquiry regarding ways to harmonize the new OTC drug labeling requirements with cosmetic labeling requirements.

As a preliminary matter, the agency notes that CTFA is not questioning the need for cosmetic-drug products to carry FDA-required labeling. Indeed, the association's members intend to continue to include all FDA-required drug labeling with their products. Pet. at 5. CTFA is, however, contesting the need for FDA to require the placement of this information in a new, standardized format.

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[2]The implementation plan for the final rule (64 FR at 13274) provides one additional year (to May 16, 2002) for products with annual sales of less than $25,000.

The new format establishes a clear, easy-to-read presentation that lists the required information in a logical hierarchy, with simple headings and subheadings to introduce major sections of the labeling. The format also includes minimum type size and graphical standards, to help ensure that consumers are able to read the required labeling comfortably, from beginning to end. And, the format is designed to allow consumers to compare similar products side-by-side, to help them recognize differences among products, and to help them select the best product to meet their needs. CTFA agrees that required information must be presented on cosmetic-drug labeling; CTFA disagrees, however, with having to present this information in the new, easy-to-read format.

A. Categorical Exemption for Small Packages

In its comments to the proposed rule, CTFA argued that the agency should exclude from the rule cosmetic-drug products sold without dosage limitations (*i.e.*, sunscreens, antidandruff shampoos, skin protectants, antimicrobial soaps and washes, and antiperspirant/deodorant products). For the reasons outlined in the final rule, the agency declined to accept CTFA's proposal. 64 FR at 13268-70. As a result, CTFA argues that "an objective small package exemption standard" is now vitally important, to minimize "the negative impact of certain of the new format requirements" on these and other products. Pet. at 7-8. CTFA's proposed small package standard — once triggered — would exempt products *in toto* from the new labeling format. Pet. at 8.

For the reasons discussed in the preamble to the final rule, the agency continues to believe that a *blanket* exemption for small packages is neither necessary nor appropriate. *See* 64 FR at 13267-68; *see also* 64 FR 13282-83 (finding that only about 8 percent of existing products may need to increase package size to accommodate the new labeling). This decision is consistent with the agency's overall goal of ensuring that all OTC drug labeling, irrespective of package size, is clear and readable and is "likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. 352(c). It is also consistent with the agency's estimate that any package size changes that would be needed as a result of this rule would either be very limited (*e.g.*, increasing the dimensions of an existing package by a small fraction), or could be accomplished by integrating commonly used techniques, such as the addition or extension of a fifth panel or the use of a placard and bubble-pack. *See* 64 FR at 13268, 13283. Further, as discussed in the response to CHPA's petition (attached at II.D), the agency intends to publish shortly a draft guidance that will include information on how manufacturers may seek a limited deferral of time for the purpose of completing a change in packaging to meet the requirements of the rule.

The agency also stands by its decision not to exempt from the final rule the five categories of OTC drug products identified by CTFA which are often marketed for both drug and cosmetic uses, and which usually do not bear a "dosage limitation." *See generally* 64 FR at

13268-70. The final rule sets forth the reasoning in support of the use of a standardized format for all drug products that are sold OTC to lay consumers. Also, and as the agency emphasized in the final rule, the importance of the labeling cannot be minimized – even within the categories identified by CTFA for exemption. *Id.*

For example, certain sunscreen ingredients have the potential to cause photo-allergenicity and, accordingly, bear warnings to stop use and speak to a doctor if a rash or irritation develops. Skin protectant ingredients which may not require special care in cosmetic uses (*e.g.*, petrolatum used to remove make-up), may require special care when intended for a drug use (*e.g.*, petrolatum as a skin protectant for the temporary protection of minor cuts, scrapes, and burns).[3] Antiperspirant products, which contain aluminum salts, include warnings not to apply the products to broken skin, and to discontinue use if a rash or irritation develops. Some dandruff shampoos may promote sun sensitivity, while others include specific language when labeled for use in treating seborrheic dermatitis or psoriasis. Some antimicrobial washes contain substantial amounts of alcohol and may be required to include flammability warnings. Antiseptic handwash drug products instruct not to use in the eyes and to discontinue use if irritation and redness develops, and to contact a doctor if the condition persists for more than 72 hours.

The categories of cosmetic-drug products identified by CTFA, as with all other OTC drug categories, include important labeling information that must be presented in a manner that is likely to be read and understood. The placement of this and other required information in a standard format is expected to minimize the complexity of the information and, in turn, increase the likelihood that consumers will read and focus on it. The format also will provide consumers with an important tool for comparing products to help them select an appropriate product to meet their needs. *See generally* 64 FR at 13254-55; 62 FR at 9040. For example, "Drug Facts" labeling will help consumers differentiate between products intended solely to provide a cosmetic effect (such as a non-fluoride toothpaste or a deodorant) and products that are intended to provide both a cosmetic and a drug effect (such as a flouride-containing toothpaste or an antiperspirant-deodorant).

Finally, the agency recognizes that there may be specific ingredients for which streamlined labeling requirements can be explored, to help allow for the continued marketing of these ingredients in small packages. As discussed in the final rule, the agency will consider the possibility of ingredient or category-specific small package exceptions, but only in the context of a medical and scientific review. *See* 64 FR at 13270 (noting that the agency would identify possible monograph-based accommodations for small packages for products that have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable

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[3]The application of a skin protectant over a deep wound or puncture or over an infection or laceration can lead to serious complications. Serious wounds, punctures, or infected lesions, if placed under a sealed, greasy cover may become macerated and further inflamed.

public health benefit, require no specific dosage limitation, and require few specific warnings and no general warnings (*e.g.*, pregnancy or overdose warnings)). Ingredient or category-specific arguments, such as those raised by CTFA, are best addressed within the OTC drug monographs, where the safety and effectiveness of each ingredient in the OTC Drug Review is being carefully evaluated.

Three of the five categories identified by CTFA – antiperspirants, skin protectants, and topical antimicrobial soaps and washes – are not the subject of final monographs. The agency will carefully consider the ingredients in each of these categories as it finalizes the monographs, and will seek to identify ways, where appropriate, to accommodate those ingredients that are typically marketed in small packages.

One category (sunscreens) is the subject of a monograph that published after the labeling rule. *See* 64 FR 27666 (May 21, 1999). The sunscreen monograph included several accommodations for products that are customarily packaged in small containers, are intended to be applied to limited areas of the face, and otherwise meet the characteristics discussed in the labeling rule. 64 FR 27666, 27689 (May 21, 1999). Further, in a letter dated October 1, 1999, the agency informed CTFA that the effective date for implementing the monograph for OTC sunscreen drug products will be extended to December 2002, and that the agency would consider additional accommodations as appropriate as it develops a comprehensive UVA-UVB monograph for sunscreens.

Only one category (antidandruff shampoo) is the subject of a final monograph that pre-dated publication of the OTC labeling rule. To the extent such products raise small package concerns, the agency would consider format or content accommodations through a petition to amend the monograph under 21 CFR 330.10(a)(12).

In sum, implementation of the final labeling rule need not be delayed for further consideration of a categorical or blanket small package exemption, as requested by CTFA. The agency carefully considered the needs of small package products in the final rule. The rule includes format specifications that will allow most products to bear the new "Drug Facts" labeling without requiring a change in packaging. Many of the remaining products will require only small changes in packaging to meet the requirements of the rule. With the extension of time provided in response to this petition, most products will continue to have a substantial period of time for compliance with the rule. For some specific products, even more time may be obtained through the deferral process.

B. Harmonization with Cosmetic Labeling Requirements.

The petition includes two examples to suggest that additional time is needed to allow for discussion of ways to harmonize OTC drug labeling requirements with cosmetic labeling

requirements. The first involves the listing of inactive ingredients in OTC drug products, now required under section 502(e) of the Federal Food, Drug, and Cosmetic Act (as amended by section 412 of the 1997 FDA Modernization Act). The second, which raises a type size issue, is addressed in the response to the CHPA response (*see* attached at II.C).

The final OTC drug labeling rule specifies a heading for the listing of inactive ingredients and includes several requirements for the presentation of this information. *See* 21 CFR 201.66(c)(8). Section 201.66(c)(8) also describes how to list the inactive ingredients in an OTC drug that is also a cosmetic product. Thus, an OTC cosmetic-drug product may bear one consolidated ingredient list.

CTFA notes, however, that the agency's cosmetic labeling regulations provide many different ways to present cosmetic ingredient information, and that the agency failed to include at least one of those ways in the OTC labeling rule – namely, the use of an off–the-label declaration of ingredients on a "padded sheet" or "leaflet," if the product meets several specific conditions. 21 CFR 701.3(i).

The agency declined to include this provision because it conflicts with section 502(e) of the Act, which provides that a drug is misbranded if its label does not bear inactive ingredient information on the outside container of the retail package. Section 701.3(i) also conflicts with the general approach of the final labeling rule of providing all required information in one continuous "Drug Facts" panel.

CTFA suggests in its petition that the agency wholly ignored the dual labeling concerns of the cosmetic-drug industry. On the contrary, the agency carefully considered ways to avoid duplicative labeling for such products. In particular, with respect to the ingredient listing, the agency incorporated as many of the cosmetic labeling approaches authorized under 21 CFR 701.3 as possible, while still maintaining consistency with statutory labeling requirements and the intent of the final rule. For example, 21 CFR 201.66(c)(8) incorporates by reference sections 701.3(a) and (f), as alternative ways of listing the inactive ingredients (*i.e.*, in descending order of predominance or grouped).

The agency is open to further discussion on ways to address CTFA's dual labeling concerns. The agency does not believe, however, that the petition provides a basis for delaying implementation of the final labeling rule for this purpose.

II. Conclusions

CTFA petitioned the agency seeking an extension of time to discuss several issues. According to the petition, small package issues, the exemption/deferral process, trade dress and light-on-dark printing, and the need for harmonization with existing cosmetic requirements, are

of particular importance to CTFA's members.

As discussed in the response to CHPA, the agency will provide additional guidance on the exemption and deferral process, which will include information of relevance to manufacturers who find they must change their packaging to comply with the rule. The agency has already resolved the trade dress and light-on-dark printing issue through a technical amendment, and has issued a draft guidance on the use of columns, which is also expected to help some small package products. The agency will continue to evaluate ways to convey required information as efficiently and concisely as possible. The agency also is committed to identifying within the monograph process accommodations for small package products within the categories identified by CTFA. The agency continues to find, however, that there is ample basis to decline to exclude the five categories suggested by CTFA from the new format requirements.

Finally, for the reasons outlined more fully in response to the petition submitted by CHPA, the agency will take necessary steps to extend the primary implementation date by one year, to May 16, 2002 (and the corresponding date for low volume products to May 16, 2003).

The agency has worked closely with CTFA to help ensure that OTC cosmetic-drug product labeling is legible and that the final rule is appropriate for the marketplace. We look forward to continuing to have candid, productive discussions, and to working with CTFA toward the shared goal of providing consumers with clear, concise, easy-to-read OTC labeling.

Sincerely yours,

William Hubbard

William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

cc: Bruce N. Kuhlik
Covington & Burling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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February 4, 2000

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Re: Over-the-Counter Drug Labeling (Docket No. 98N-0337/CP2)

Dear Messrs. Kuhlik and Labson:

This letter is in response to the petition submitted on October 1, 1999, on behalf of the Consumer Healthcare Products Association (CHPA). The petition, submitted under 21 CFR 10.30, requests a two-year extension of time for compliance with the agency's final rule on the labeling of over-the-counter (OTC) drug products, 21 CFR 201.66. *See* 64 FR 13254 (Mar. 17, 1999). The rule established a standardized format for presenting required OTC drug labeling information. It is intended to assist consumers in reading and understanding OTC drug labeling, in selecting among various products, and in using these products safely and effectively.

The rule went into effect on May 16, 1999.[1] However, for the large majority of products, compliance with the rule is not required until, at the earliest, May 16, 2001 (the "primary implementation date"). *See* 64 FR at 13274.

CHPA requests a two-year extension of the primary implementation date to May 16, 2003. Also, for those products that must immediately begin to comply with the rule (namely, OTC drug products approved after May 16, 1999, under new drug or abbreviated new drug applications), CHPA requests a stay of the rule "until FDA resolves currently open implementation issues and companies are given sufficient time to incorporate FDA's clarification into the label . . . ." CHPA Petition ("Pet.") at 3.

The primary basis for the petition is the claim that "[c]ritical issues concerning the label formatting under the new rule are unresolved," and that companies cannot begin converting to the new format until these issues are resolved. Pet. at 7. As noted in the petition, the agency's economic impact analysis in support of the final rule generally assumes a 2-year implementation

[1]On April 15, 1999, the agency published a correction to the effective date of the rule (64 FR 18571).

period. Pet. at 11 (*citing* 64 FR at 13272). Because CHPA asserts that manufacturers have been hindered from moving forward with the redesign of their labeling, the petition argues that FDA must extend the primary implementation date. Otherwise, according to CHPA, the agency's economic assumptions in support of the rule are no longer valid. Pet. at 11-12.

The petition lists the following "open" issues:

- the use of columns in labeling
- protection of "trade dress"
- the use of type sizes smaller than 6.0 points
- the labeling of single use and convenience packages
- the use of "extended text labeling" and
- the use of the exemption process under 21 CFR 201.66(e)

According to CHPA, the industry raised these issues in comments to the proposed rule, or immediately after publication of the final rule, but the issues have remained unresolved. Pet. at 2. The petition also states that the final rule included several "new elements" that require further discussion with the agency, such as the placement of a telephone number in the required "Drug Facts" panel and the use of "Drug Facts (continued)" labeling. Pet. at 3.

To account for the time that CHPA claims has been "lost," as well as the time CHPA expects will be required to resolve these issues, the petition seeks a two-year extension of the primary implementation date, as well as the stay described above.

The agency has carefully considered the petition, and all relevant information related to it. For the reasons discussed below, the agency is denying the petition in part and granting it in part. In an upcoming issue of the Federal Register, FDA will publish notice of an amendment to the implementation plan to extend the primary implementation date by one year, to May 16, 2002 (and the corresponding implementation date for low volume products to May 16, 2003[2]). The request for a stay of the rule, for products marketed under new drug or abbreviated new drug applications approved after May 16, 1999, is denied.

I. Procedural History

FDA has been considering the need for OTC drug labeling readability standards for nearly ten years. In 1990 the Pharmacists Planning Service (PPS) petitioned the agency to set print size and print style standards for OTC drug labeling to improve readability (Docket No. 90P-0201). On March 6, 1991, FDA published the PPS petition in the Federal Register and

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[2]The implementation plan for the final rule (64 FR at 13274) provides one additional year (to May 16, 2002) for products with annual sales of less than $25,000.

solicited comments from the public (44 FR 9363).

On March 25, 1991, CHPA (then known as the Nonprescription Drug Manufacturers Association) issued voluntary Label Readability Guidelines to help address consumer demand for improved OTC drug labeling. On April 9, 1991, FDA extended the comment period on its March 6, 1991, notice, to allow the public to comment on the CHPA Guidelines.

On August 16, 1995, FDA published a notice of public hearing under 21 CFR part 15 and requested additional comments on the presentation of OTC drug labeling (60 FR 42578; Docket No. 95N-0259). The public hearing, held on September 29, 1995, included testimony from several experts on label readability, testimony from a representative of the National Consumers League on OTC drug readability, and testimony from CHPA and The Cosmetic, Toiletry, and Fragrance Association (CTFA).

On February 27, 1997, FDA published a proposed rule to establish standardized format and content requirements for OTC drug labeling (62 FR 9024; Docket Nos. 96N-0420, 95N-0259, 92N-454A, and 90P-0201). On May 8, 1997, FDA held a public feedback meeting with industry and other interested persons to discuss the proposed rule. On June 19, 1997, FDA extended the comment period on the proposed rule to October 6, 1997 (62 FR 33379), and on July 14, 1997, the agency presented several OTC labeling issues to FDA's Nonprescription Drugs Advisory Committee.

In December 1997 and February 1998 the agency published two studies of OTC labeling formats ("Evaluation of Revised Formats for OTC Drugs" (62 FR 67770, Dec. 30, 1997) and "Evaluation of Proposed OTC Label Format Comprehension Study" (63 FR 7331, Feb. 13, 1998)), and re-opened the administrative record to allow for comment on these studies. CHPA filed extensive comments on the proposed rule as well as the two studies. On March 17, 1999, after carefully considering the comments and all relevant information, FDA issued the final rule on OTC labeling (64 FR 13254; Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201).

Following publication of the rule, the agency held a series of "feedback" and "workshop" meetings, to help the industry begin its transition to the new labeling format. These included public meetings on April 23, June 29, August 24, September 17, and November 23, 1999. At each of these meetings, and in a series of letters to the agency (attached to CHPA's petition), CHPA raised a variety of questions and concerns about the rule. CHPA made a detailed presentation at the June 29 meeting recommending that the agency allow the use of columns to present required information. At the August meeting, CHPA and CTFA raised concerns about the impact of the rule on the use of certain color combinations or "trade dress" in OTC drug and drug-cosmetic packaging. And, at the September and November meetings, CHPA focused in particular on type size issues and other concerns associated with small package products.

On October 1, 1999, CHPA submitted its petition (Docket No. 98N-0337/CP2) seeking a two year stay of the primary implementation date for the rule, and on October 22, 1999, CTFA submitted its petition (Docket No. 99P-4617/CP1) requesting essentially the same relief as CHPA.

On December 1, 1999, FDA issued a notice of availability of a draft guidance titled "Labeling of Over-the-Counter Human Drug Products Using a Column Format" (64 FR 67291), to address questions regarding the use of columns under the new format. On January 3, 2000, FDA issued a technical amendment to the rule to address, among other points, confusion over the use of "light" and "dark" shades of print and the related "trade dress" issue (65 FR 7).

II. Analysis

A. Columns

The labeling format adopted by the agency in the proposed and final rule generally favors a vertical presentation, to enhance readability, minimize the potential for confusion, and facilitate the side-by-side comparison of products. CHPA has asked for additional time to discuss whether the required labeling may be presented using a column format, including the use of "columns within columns." For example, after the agency published the final rule, CHPA recommended at several feedback meetings that manufacturers should be permitted to divide the information under each "Drug Facts" heading into columns.

On December 1, 1999, the agency issued a draft guidance document showing how the required labeling may be presented in a column format, in a manner that is consistent with the requirements of the final rule. 64 FR 67291. The guidance notes, however, that the "columns within columns" approach recommended by CHPA generally would not be permitted under the rule. Comments on the guidance were due January 31, 2000, and the agency intends to finalize the guidance as quickly as practicable.

The agency does not agree with CHPA that the request for "clarification" on the use of columns warrants a further extension of the primary implementation date. As shown in the draft guidance, the final rule permits the use of columns, provided the essential structure and flow of the "Drug Facts" panel is retained. The agency also notes that CHPA did not raise in its comments to the proposed rule the various ways in which it now seeks to use columns to present required drug labeling.[3] The procedurally appropriate step, if CHPA believes the rule should be

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[3]According to the petition, CHPA and other commentators "referred to columns" in comments to the proposed rule. Pet. at 8. CHPA did not, however, direct the agency to any specific discussion of this issue in the comments. CHPA's "Guidelines for OTC Labeling" include a brief description of the use of columns. In one footnote in CHPA's lengthy written

amended to allow more ways to use columns, would be to file a petition under 21 CFR 10.25(a).

B. Trade Dress

The agency believes the technical amendment document, published on January 3, 2000 (65 FR 7), resolves the questions that CHPA and others raised, following publication of the final rule, about the use of certain light on dark combinations of print. Therefore, an extension of the primary implementation date is not needed to allow for further discussion of this issue.

C. Type Size

The final rule requires a minimum type size of 6 points when presenting information in the "Drug Facts" labeling. 21 CFR 201.66(d)(2); *see generally* 64 FR at 13264-65. Since publication of the rule, CHPA has made several presentations on the issue of type size. CHPA estimates that as many as 30 percent of OTC stock keeping units cannot comply with the rule, and that type size is the most significant factor in determining whether the new labeling will fit onto an existing package.

Accordingly, CHPA has asked the agency to delay implementation of the rule to consider the use of smaller type sizes, especially for small packages. CHPA has argued that data in the record support a minimum type size of 4.5 points. Also, CHPA insists the agency lacks an adequate basis to require a 6 point minimum. Finally, CHPA has continued to raise the need for "type size parity" across all FDA regulated products. *See, e.g.*, Ex. 1; Ex. 2 at 6, slide 12. For the reasons discussed below, the agency does not agree that additional time is needed to consider type size issues.

1. General Factors

FDA has been considering the issue of type size for OTC drug products since at least 1990, when the Pharmacists Planning Service (PPS) petitioned FDA to set minimum standards for OTC drug labeling. Among other things, the petition emphasized that significant numbers of older adults have been hospitalized due to adverse drug reactions involving OTC drugs, and that most people (especially the elderly) are unable to read the print on OTC drug labeling. 62 FR at

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comments to the proposed rule, columns were listed as one many factors that may affect readability. The agency, however, found no substantive discussion by CHPA of the use of columns or the idea of allowing information under certain headings to be divided into columns ("columns within columns"). None of the labels appended to CHPA's comments, in which CHPA suggested modifications to FDA's proposed format, shows the use of "columns within columns." *See* CHPA comments, App. E. The "Recommended Format" submitted by CHPA with its comments, App. F, does not show or suggest the use of columns.

9028.

The issue of assuring readability for elderly consumers has been a significant consideration throughout this process. Although the elderly comprise 12 to 17 percent of the population, they consume about 30-50 percent of all drug products. 62 FR 9024, 9027. As discussed in a 1994 study, a significant number of elderly consumers (60 yrs or older) could not adequately see the print on certain OTC product labels due in part to small type sizes and horizontal letter compression. *See* 62 FR at 9028 (*citing* Ex. 3); *see also* Sept. 29, 1995, Public Hearing on Over-the-Counter Drug Labeling Transcript at 31, FDA Docket No. 95N-0259 (hereafter Transcript) ("[T]he elderly are more likely to use over-the-counter medications, more likely to have a higher incidence of medical conditions that may be adversely affected by the inappropriate use of medications, and more likely to be taking other medications that may have adverse interactions with certain over-the-counter medications.").

Second, the goal of this proceeding has been to set standards for clear, consistent, easy-to-read drug labeling, and to minimize the "cognitive load" that drug labeling places on lay consumers. *See, e.g.*, 64 FR at 12355. Under section 502(c) of the Federal Food, Drug, and Cosmetic Act, drug labeling must be sufficiently prominent and conspicuous "as to render it *likely to be read and understood* by the ordinary individual . . ." 21 U.S.C. 352(c) (emphasis added); *see* 64 FR 9043. Marginal type sizes, or type sizes that are legible only at threshold levels, make it *less likely* that a consumer will begin to read the labeling, let alone read it thoroughly.

Third, as discussed below, the agency carefully considered industry practices in setting a minimum type size for OTC drug labeling, to help ensure the adoption of an attainable standard.

2. CHPA's Approach

CHPA's central study in support of the argument that 4.5 point type is an appropriate minimum standard for OTC drug labeling is Sidney Smith's 1979 article, "Letter Size and Legibility" (attached as Ex. 4).[4]

Smith studied "display legibility" using a variety of test materials, none of which appears to have included drug labeling. Ex. 4 at 665. Some of Smith's samples consisted only of a single word. *Id.* at 667. Moreover, the subjects in the study were asked only to identify the

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[4]CHPA referenced the Smith study in its comments to the proposed rule (*see* CHPA comments to proposed rule, App. H.) and in correspondence with the agency prior to the proposed rule. *See, e.g.*, Ex. 5. Although Smith and the other studies discussed in this section are already part of the record of this proceeding, the agency them as exhibits to this response, for the convenience of the reader.

absolute "legibility limit" for a given piece of display material. *Id.* at 666 ("The only measure taken was the legibility limit."). Viewers were not asked to specify a comfortable or preferred viewing distance, nor were they asked to identify the distance from which the material could be read with ease. Also, Smith did not record the age of his test subjects. There is even some suggestion that most may have been under 30 years of age. *Id.* at 668.

In contrast, the focus of this proceeding has been on labeling that consumers are *likely* to read and understand, from beginning to end, rather than on the threshold levels at which consumers can first begin to see printed material. *See* 21 U.S.C. 352(c). There is an important distinction between what a consumer is able to see, and what a consumer is likely to try to read – from beginning to end, with minimal error. As Smith cautioned:

> In practical display applications, however, it is not wise to design to the limits of visual acuity. An engineer will not design a bridge to meet minimum loads, but instead multiplies the strength of supporting trusses by some safety factor so that the bridge can be crossed with greater confidence. A display designer should also include some safety margin, specifying a letter size large enough to be read with confidence.

Ex. 4 at 662 (emphasis added).

Finally, following publication of the final rule, CHPA has continued to reference Smith for the idea that "98% of test subjects could read 4.5 point type at a distance of 13 inches." Ex. 6 at 7. In fact, Smith found that 98 percent of his test subjects could read copy that subtended a visual angle of 0.0046 radians.

According to CHPA, a visual angle of 0.0046 radians corresponds to a letter height of 0.06 inches at a viewing distance 13 inches,[5] and a letter height of 0.06 inches corresponds to a point size of 4.5. Ex. 5 at 2. However, a type size of about 6 to 8 points would be needed to present text that is generally 0.06 inches in height. This is because, as CHPA has stated, letters set in 4.5 point type are *not* 0.06 inches high.[6] *Id.* CHPA's submissions to the agency state that point size is a measure of the total height from the bottom of the lowest letter to the top of the highest letter, and that the upper case letters in 4.5 point type are usually only .042 inches or about 3 points. *Id.* Lower case letters in 4.5 point type would be even smaller – about half the

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[5]Although CHPA assumes a viewing distance of 13 inches, other materials cited by CHPA suggest 16 inches as the appropriate benchmark for "reading distance." Ex. 5 at 3 (citing Holt, G., *et al..*, "OTC Labels: Can Consumers Read and Understand Them?" 11 *American Pharmacy* 51 (Nov. 1990)). Using 16 inches, the letter height would be 0.0736 inches.

[6]Type sizes are designated in units called points. There are approximately 72 points to one inch. Each point measures 0.0138 of an inch.

point size or 0.03 inches. Therefore, to achieve the level of legibility that CHPA relies on from the Smith study, one would need to use text that is more than 6 points (assuming a viewing distance of 13 inches and the use of all upper case letters); or 8 points (assuming a viewing distance of 13 inches and the use of primarily lower case letters)[7]. Added to that, Smith found that letter sizes intended for close viewing, such as consumer labeling, may need to be larger in size than one would derive from a measure of the limits of visual acuity. *Id.* at 668.[8]

For these reasons, the agency disagrees with CHPA that the Smith study supports the use of 4.5 point type in OTC drug labeling. Indeed, Smith would support the use of a larger type size (6 point *or greater*) for consumer-directed drug labeling.

CHPA has also directed the agency to "the definition of visual acuity" to support the use of 4.5 point type in OTC drug labeling. *See, e.g.*, Ex. 5; Ex. 7. According to CHPA, a person with 20/20 vision can read text 0.019 inches high at a distance of 13 inches (equal to 1.7 point type), a person with 20/40 vision can read text 0.037 inches high (equal to 3.3 point type), and a person with 20/55 vision, according to CHPA, would be able to read 4.5 point type. *See* Ex. 5 at 3; *see also* Ex. 7 at 1.

For reference, the following sentences are set in 1.7, 3.3, and 4.5 point type:[9]

This sentence is in 3.3 point Times New Roman type.

This sentence is in 4.5 point Times New Roman type.

Each of these type sizes – if one accepts CHPA's assumptions – represents the threshold limit at which a person with a given visual acuity can begin to see text. They do not represent type sizes which can be read with ease. *See* Ex. 4 at 662 ("Design standards for visual displays generally

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[7]The OTC labeling rule requires primarily the use of *lower case* letters. *See* 21 CFR 201.66(d)(1).

[8]Smith also found that 100 percent of his subjects could read a letter size of 0.007 radians. *Id.* at 667. Using CHPA's method of converting this figure to a point size, Smith found that 100 percent of his test subjects were able to read 6.6 type at a distance of 13 inches. If one adjusts for the use primarily of lower case letters and a viewing distance of 16 inches, one would need to use a type size of more than 12 points to attain the level of legibility found by Smith.

[9]The following sentences are set in 6, 8, and 10 point type:

This sentence is in 6 point Times New Roman type.

This sentence is in 8 point Times New Roman type.

This sentence is in 10 point Times New Roman type.

recognize the need for a safety margin, and specify letter sizes larger than those at the limits of visual acuity."). Moreover, if one adjusts for a standard reading distance of 16 inches, and takes into account the use of primarily lower case text, each of these types sizes would have to be adjusted *upward*. The agency also notes that type size is only one factor that determines readability (*see* 62 FR at 9028), and that OTC labeling – which often consists of extensive and complex text – can be especially demanding for the reader.[10]

At best, CHPA's approach may help to establish a base from which to develop specific minimum type sizes for specific categories of products. As discussed below, the agency has allowed the use of the smallest readable type size in certain contexts (*see* section II.C.4, below). For OTC drug labeling, however, there is ample basis to require a larger size.

3. The Industry Standard

A key starting point for FDA in setting an appropriate minimum type size for OTC drug labeling was to consider current industry practice. At the agency's September 1995 public hearing, CHPA testified that most of the OTC drug industry had already adopted 6 points "*or better*" as the standard:

> We have done a label survey of our members looking at 2,000 labels and over 95 percent were at six point or better, and I think one of the practicalities is that there is a huge amount of information that is required on some of these labels. The particular diphenhydramine prototype that is in Appendix C [is] done at around six points, if you do that at seven points [it] will not fit the package. So, we recommend adopting the current industry practice."

Transcript at 108 (emphasis added).[11]

The agency, in turn, incorporated the industry standard into the OTC labeling rule after hearing additional testimony and after reviewing several studies confirming the readability of 6

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[10]In contrast, a study submitted by the American Pharmaceutical Association with a comment to the proposed rule evaluated the readability of 9 OTC drug labels with type sizes ranging from 4 to 11 points. Ex. 8. The study found that subjects needed at least 20/30 vision to read OTC drug labeling in 4 point type and 20/40 vision to read labeling in 6 point type. Only one of the labels (presumably, a label set in 11 point type) could be read accurately by those with a visual acuity of 20/50. Ex. 8 at 51.

[11]In its written submission to the public hearing, CHPA noted that "as an absolute minimum, 4.5 print type is reasonable for OTC labels, though not often used. Six point type is commonly used and preferred." Ex. 9 at 17.

point type for OTC drug products. For example, the National Consumers League (NCL) testified at the September 1995 hearing on an "investigative survey" of OTC drug labeling. In the study, 60 adults were asked to assess the readability of OTC products ranging in size from 4.0 to 6.5 point type. Ex. 10 at 3. As the agency noted in the rulemaking, NCL found that only 32 percent of the subjects age 51 and older were able to read OTC drug labeling set in 4.5 point type. 64 FR at 13265. Among the labels tested by NCL, the one set in 6.5 point type proved best, with 75 percent of the subjects age 51 and older, and 94 percent of the subjects under age 51, able to read it. On the other end of the spectrum, none of the subjects age 51 and older was able to read one of the labels set in 4 point type, and only 25 percent of the subjects under age 51 were able to read the label. Ex. 10 at 8. Thus, the NCL survey raises concerns about the readability of type sizes around a 4.5 point range and, at the same time, supports the use of type sizes in the 6.5 point range.[12]

The Watanabe study, cited by the agency in the rulemaking, also supports the use of a 6 point or better type size. Dr. Watanabe sampled 92 consumers, 60 years of age and older, using three labels – two set in 3.3 point type and one set on 6.7 point type. Ex. 3 at 33; *see also* 64 FR at 13265. In addition to showing that horizontal letter compression is a significant factor in determining readability, the Watanabe study concluded that a vertical type size of at least 6.7 points should be used in OTC drug labeling.[13]

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[12]At the November 23, 1999, feedback meeting, CHPA stated that the NCL study supported the use of less than 6 point type. Ex. 2 at 6, slide 11. The 5 point label tested in the NCL survey performed at the same level as one of the labels set in 6 point type. Forty-eight percent of the subjects age 51 and older either could not see the text on either label or found it too hard to read. Factors, such as color contrast, layout, or letter compression, may have accounted for these results. However, a second label tested by NCL, set in 6 point reverse type significantly outperformed the other labels. Sixty-eight percent of the older subjects and 91 percent of the younger subjects were able to read it. Ex. 10 at 9.

[13]At the November 23, 1999, feedback meeting, CHPA asserted that the Watanabe study "showed little difference in readability between 6.7 and 3.3 point type." Ex. 2 at 6, slide 11. We disagree. In a comparison of one of the 3.3 point labels to the 6.7 point label, Dr. Watanabe found that approximately 30 percent of the subjects were unable to either start *or finish* reading the 3.3 point label. Only 2 percent were unable to read the 6.7 point label. In a comparison of the other 3.3 point label with the 6.7 point label, Dr. Watanabe found only a small statistical difference in readability, concluding that the horizontal letter compression on the 3.3 point label compensated significantly for the smaller type size. However, Dr. Watanabe also concluded that "subjective observations by both subjects and researchers indicate that greater effort was expended in reading the smaller print [on this label]," and that "[t]his suggests that letter size approximating the [6.7 point type size] should be used." Ex. 3 at 35.

The agency also received numerous comments from consumers, consumer groups, and health professionals in favor of adopting 6 point or larger as the minimum standard. *See, e.g.*, FDA Docket No. 96N-0420, C103; C104; C467. Consumer preferences and comments are significant in this proceeding, given the statutory directive to develop labeling that consumers will be "*likely*" to read.

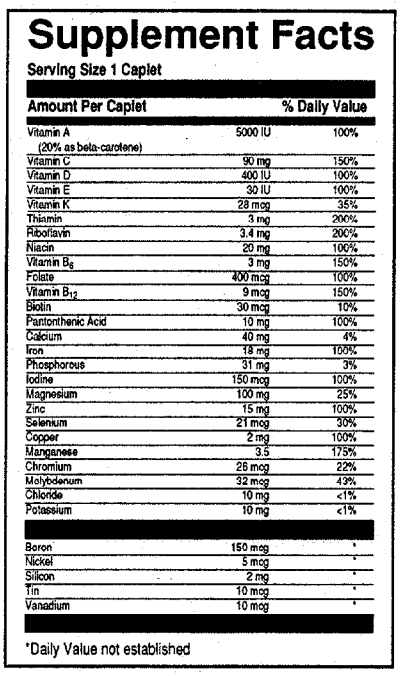
4. "Parity"

Finally, at the November 23, 1999, feedback meeting and at several other public meetings following the final rule, CHPA has emphasized the need for "consistency and fairness across FDA regulated consumer products." As noted in comments to the proposed rule, the agency allows certain dietary supplement products to use a minimum 4.5 point type. 21 CFR 101.36(i). The agency has also allowed letters no less than 1/16th of an inch for the listing of ingredients in cosmetic products, or 1/32 of an inch in limited circumstances. 21 CFR 701.3(b) and (p).

The agency carefully considered this issue in the final rule and did not find it to be decisive. 64 FR at 13265. As the agency outlined in the rule, factors such as the nature and quantity of the information required, and the manner in which the information is presented, may allow for the use of different labeling specifications. In some contexts, there is often little required information presented on the labeling (either a few words or a single sentence), and there is adequate white space to enhance readability, putting less of a demand on the user to read the information.

This point is illustrated below. Figure 1 shows a multi-ingredient dietary supplement product with the required text presented in 4.5 point type, compared with a multi-ingredient OTC drug product. The OTC drug product follows the modified format permitted under 21 CFR 201.66(d)(10), except that for purposes of illustration the drug product uses 4.5 point type to present the required text rather than the required 6 point minimum. Figure 2 compares the multi-ingredient OTC drug product in 4.5 point type versus 6 point type. Figure 2 illustrates the benefit of a larger type size in OTC drug labeling. Both figures use optimal color contrast (black text on a non-glossy white background).

Figure 1

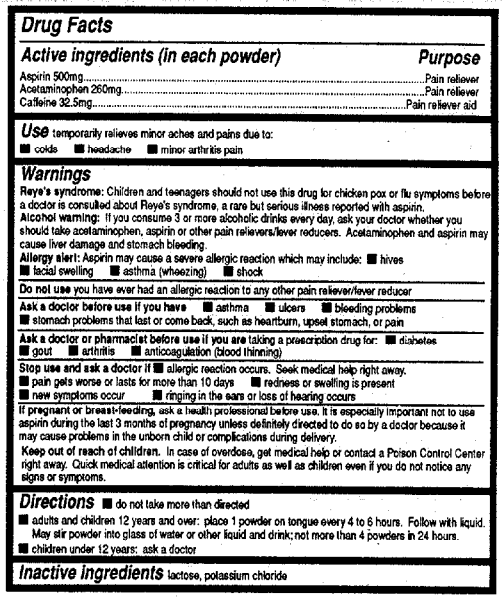


Supplement Facts

Serving Size 1 Caplet

Amount Per Caplet		% Daily Value
Vitamin A (20% as beta-carotene)	5000 IU	100%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Vitamin K	28 mcg	35%
Thiamin	3 mg	200%
Riboflavin	3.4 mg	200%
Niacin	20 mg	100%
Vitamin B_6	3 mg	150%
Folate	400 mcg	100%
Vitamin B_{12}	9 mcg	150%
Biotin	30 mcg	10%
Pantonthenic Acid	10 mg	100%
Calcium	40 mg	4%
Iron	18 mg	100%
Phosphorous	31 mg	3%
Iodine	150 mcg	100%
Magnesium	100 mg	25%
Zinc	15 mg	100%
Selenium	21 mcg	30%
Copper	2 mg	100%
Manganese	3.5	175%
Chromium	26 mcg	22%
Molybdenum	32 mcg	43%
Chloride	10 mg	<1%
Potassium	10 mg	<1%
Boron	150 mcg	*
Nickel	5 mcg	*
Silicon	2 mg	*
Tin	10 mcg	*
Vanadium	10 mcg	*

*Daily Value not established



Drug Facts

Active ingredients (in each powder) — **Purpose**

Aspirin 500mg ..... Pain reliever
Acetaminophen 250mg ..... Pain reliever
Caffeine 32.5mg ..... Pain reliever aid

Use temporarily relieves minor aches and pains due to:
■ colds ■ headache ■ minor arthritis pain

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported with aspirin.
Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen, aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.
Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

Do not use you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have ■ asthma ■ ulcers ■ bleeding problems ■ stomach problems that last or come back, such as heartburn, upset stomach, or pain

Ask a doctor or pharmacist before use if you are taking a prescription drug for: ■ diabetes ■ gout ■ arthritis ■ anticoagulation (blood thinning)

Stop use and ask a doctor if ■ allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts for more than 10 days ■ redness or swelling is present ■ new symptoms occur ■ ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions ■ do not take more than directed
■ adults and children 12 years and over: place 1 powder on tongue every 4 to 6 hours. Follow with liquid. May stir powder into glass of water or other liquid and drink; not more than 4 powders in 24 hours.
■ children under 12 years: ask a doctor

Inactive ingredients lactose, potassium chloride

14 point Helvetica Regular Bold Title
6 point Helvetica Narrow Bold Headings
6 point Helvetica Narrow Subheadings
4.5 point Helvetica Narrow Text
5.5 point Leading

8 point Helvetica Narrow Bold Italic Title
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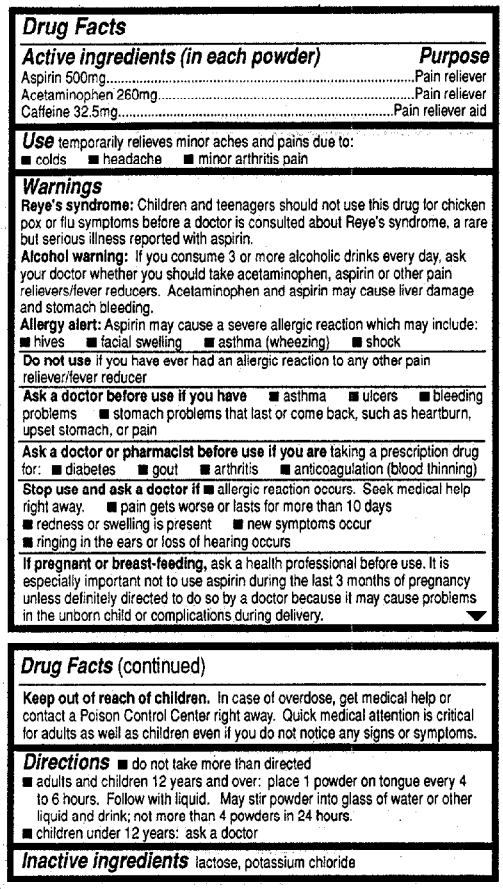
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

Figure 2



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Drug Facts (continued)

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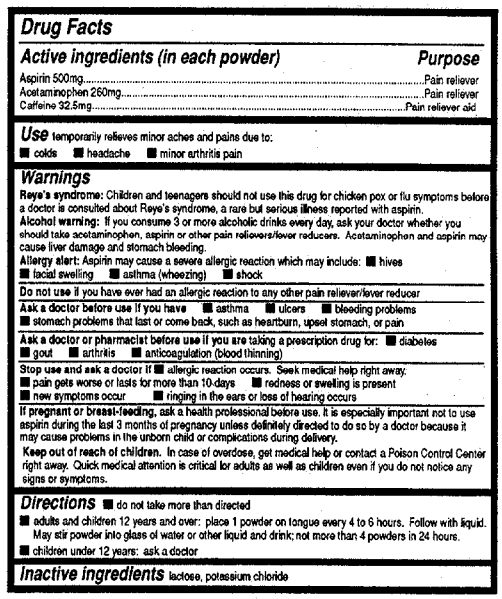
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6.5 point Leading



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Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

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Inactive ingredients lactose, potassium chloride

8 point Helvetica Narrow Bold Italic Title
7 point Helvetica Narrow Bold Italic Headings
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

As the agency found in the final rule (and as illustrated here), the overall "Supplement Facts" layout, including the tabular style and the limited amount of explanatory text, allows for the use of a smaller type size in limited circumstances.

The agency also notes that in other instances it has required 6 point or larger type. For example, the agency established a 10 point minimum type size for approved patient labeling for human prescription drug and biological products (*i.e.*, "Medication Guides"). 21 CFR 208.20(a)(4); *see also* 21 CFR 610.62 (requiring the use of 12 point and 18 point type when designating antibodies in certain biologic labeling). The minimum type size for food nutritional labeling for most products is 8 point type for certain information on the label and 6 point type for all other information. Small packages (less than 12 sq. inches) may opt not to present nutritional information. *See* 21 CFR 101.9(j)(13)(i). However, small packages that present nutrition information must use a minimum of 6 point type or all upper case letters of 1/16 inches in height. 21 CFR 101.9(j)(13)(i)(B).

Finally, for various warnings and other statements required on some FDA-regulated products, a type size or letter height of 1/16th of an inch has been required. *See, e.g.*, 21 CFR 101.93(e) ("letters of a type size no smaller than one-sixteenth inch"); 310.516(c)(1) ("minimum letter size shall be one-sixteenth of an inch in height . . . letter heights pertain to the lower-case letter 'o' or its equivalent that shall meet the minimum height standard"); 701.3(b) ("letters not less than 1/16 of an inch in height"); 740.2(a) ("in no case may the letters and/or numbers be less than 1/16 inch in height.").[14]

In short, the agency considered the labeling specifications for other product categories in developing the final OTC labeling rule. The agency also considered, however, the unique demands of OTC drug labeling, along with the strong trend in the OTC drug industry toward 6 point type, and determined that a type size larger than that allowed in limited circumstances for other categories of products such as dietary supplements was justified and reasonable.

* * *

The agency has carefully reviewed the issue of type size, including the points and materials CHPA highlighted in comments to the proposed rule and in correspondence and feedback meetings over the last several months. The agency concludes that there is no need to delay implementation of the rule to continue to consider this issue.

D. Single Use Packages, Convenience Packages, and Extended Text Labeling

The petition states that additional time is needed to resolve the labeling of single use and

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[14]Applying the analysis discussed in section C.2 of this response, if the minimum letter size permitted is 1/16 of an inch, a type size as large as 8 or 9 points may be needed in some instances to ensure that the smallest letter is no smaller than 1/16 of an inch. The limited instance in which the agency has allowed 1/32 inch type (21 CFR 701.3(p)) may require about 4.5 point type.

other convenience packages, and to address technical issues associated with the use of "extended text labeling." According to presentations made by CHPA at several recent feedback meetings, single use products and "convenience-sized" products in particular are having difficulty fitting the new format onto existing packaging. These categories, according to CHPA, account for between 1 and 2 percent of the OTC market. Ex. 2 at 13, slide 26.

The agency anticipated in its final rule that there would be a small percentage of products that would have difficulty integrating the new format into existing packaging and labeling. The agency's research leading up to the final rule estimated that 8 percent of currently marketed OTC drug products would require an increase in labeling space to accommodate the new format. As a result, the agency included within its final economic impact analysis an estimate of the additional re-packaging costs that some firms may bear as they seek to integrate the new format. *See generally* 64 FR at 13282-83; Eastern Research Group, Inc., "Cost Impacts of the Over-the-Counter Pharmaceutical Labeling Rule," in Docket No. 96N-0420.

CHPA acknowledges there are packaging options for single use and convenience products that would permit use of the new labeling. Ex. 2 at 14, slide 27. Several of these options are commonly in use, such as bubble packs mounted on hang cards and the bundling of rolled products in blister packs. CHPA, however, has asked for a series of follow-up meetings to discuss these and other options, and has also asked for additional time to discuss whether single use or convenience products may be eligible for type size or other format exemptions. Ex. 2 at 14, slide 28.

For the reasons discussed in section II.C. above, the agency does not believe that a type size exemption requires further consideration at this time, particularly where there are several packaging options available that would allow for presentation of the required format using the standards in the final rule. The agency does expect, however, that the column format option described in the December 1, 1999, draft guidance document may help some manufacturers maximize their available labeling space.

For those manufacturers who, as a result of the new labeling rule, must implement a change in package size or configuration, the agency intends to outline in a forthcoming guidance several circumstances in which the agency is likely to provide additional time (*i.e.*, a "deferral") under 21 CFR 201.66(e) in which to make such changes. The final rule allows for product-specific exemptions or deferrals, upon a showing that one or more of the labeling requirements is inapplicable, impracticable or, for a particular product, contrary to public health or safety. 21 CFR 201.66(e). The agency stated in the final rule that it does not expect to routinely grant an exemption or deferral solely because a product claims to be too small to meet the requirements of the rule. 64 FR at 13268. This is consistent with the agency's overall goal of ensuring that all OTC drug labeling, irrespective of package size, is clear and readable and is "likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21

U.S.C. 352(c). It is also consistent with the agency's estimate that any package size changes that would be needed as a result of this rule would either be very limited (*e.g.*, increasing the dimensions of an existing package by a small fraction), or could be accomplished by integrating commonly used techniques, such as the addition or extension of a fifth panel or the use of a placard and bubble-pack. *See* 64 FR at 13268, 13283.

The agency will, however, consider good faith, product-specific requests for a deferral of time for the purpose of completing a change in container size or packaging, in order to meet the requirements of the rule. For example, if a firm requires additional time to complete stability testing on a new immediate container, where it is shown that the existing container could not comply with the new format, the agency would consider a time-limited deferral. The agency will provide additional information in a forthcoming guidance on the use of the deferral process to obtain more time to complete a change in packaging. The agency expects to discuss in the guidance the use of the deferral process by those who wish to use an extended text mechanism that may require new machinery or new studies, such as a peel back panel, to meet the requirements of the rule. Following issuance of a draft guidance, the agency will solicit written comments before issuing a final document.

Through these additional steps, the agency believes it will be able to address concerns regarding the use of the new labeling format on single use and convenience products, and the use of extended text labeling. The petition has not shown that a further extension of time to allow for consideration of these issues is required.

E. Exemptions and Deferrals

The petition asks for additional time while the agency resolves questions that have been raised regarding the exemption and deferral process allowed under section 201.66(e) of the final rule (21 CFR 201.66(e)).

Although the petition does not elaborate on this point, the agency is aware that CHPA and CTFA have asked in public meetings and in correspondence for guidance on the procedures to be followed in requesting an exemption under § 201.66(e). Among other things, CHPA and CTFA have inquired as to the length of time it will take the agency to answer a request for exemption, and what steps might be taken to expedite the review of a request. They have also asked whether an appeal process is available, or whether the initial decision on the request for exemption represents "final agency action."

Second, they have asked for guidance on the standard the agency will apply in reviewing requests for exemption, and whether there are certain types of requests that are likely to receive a favorable response from the agency. CHPA and CTFA have also asked whether there are categories of exemptions that could be handled through an abbreviated process, such as through

the submission of a "notification" to FDA.

Finally, CHPA and CTFA have expressed concern that the exemption process may require the submission of trade secret or confidential commercial information, and that the process outlined under § 201.66(e) does not provide a mechanism for protecting such information from disclosure.

The agency is working on a forthcoming guidance document that will provide additional information in response to these questions. The agency notes, however, that lack of a guidance has not prevented several companies (both small and large) from submitting applications for exemption. The agency has already processed a number of these requests and is prepared to continue doing so as expeditiously as possible.

F. Other Issues

CHPA has also raised a number of other issues with the agency since publication of the final rule. As noted in the petition, CHPA has asked whether the agency would grant exemptions from the "Drug Facts (continued)" requirement, to help products fit the new labeling within existing packaging. CHPA has also asked for clarification about the placement of a manufacturer's telephone number on the labeling.

Neither of these issues warrant a further extension of the primary implementation date. For those few products that may benefit from an exemption from the "Drug Facts (continued)" labeling requirement (21 CFR 201.66(c)(1)), or from the required location for the placement of a telephone number (21 CFR 201.66(c)(9)), the agency will consider product-specific requests through the exemption process allowed under section 201.66(e). After the agency has gained additional experience in reviewing specific applications for exemption, it will consider whether additional guidance would be helpful.

III. Conclusions

Most of the issues raised in the petition (columns, the exemption process, the labeling of single use and convenience products) have been addressed or will soon be addressed through the agency's guidance process. *See generally* 62 FR 8961 (Feb. 27, 1997). One issue (trade dress) was addressed through an amendment to the final rule. The remaining issues (*e.g.*, the placement of a telephone number or the use of the "Drug Facts (continued)" title) do not present a significant obstacle toward industry-wide implementation of the new labeling format, as demonstrated by the large numbers of products that are able to comply with the rule. Indeed, as the petition suggests and as CHPA has noted at several recent feedback meetings, the new labeling format can be incorporated into a large majority (70-80 percent) of existing products.

Based on the agency's evaluation, we believe the figure is significantly higher.[15]

For these reasons, the agency concludes that a stay of the rule, or a blanket extension of two years, is excessive and is not consistent with the public's interest in having clear, readable OTC drug labeling. However, in recognition of the fact that there are several guidance documents that may prove helpful in the transition to the new format, and that at least one (on exemptions and deferrals) has yet to issue, the agency concludes that an extension of the May 2001 primary implementation date by one year to May 16, 2002 (and the corresponding implementation date for low volume products to May 16, 2003) is justified.

The agency has worked closely with CHPA to help ensure that OTC drug product labeling is legible and that the final rule is appropriate for the marketplace. We look forward to continuing to have candid, productive discussions, and to working with CHPA toward the shared goal of providing consumers with clear, concise, easy-to-read labeling.

Sincerely yours,

William Hubbard

William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

cc: Robert P. Brady
Hogan & Hartson

[15] *See, e.g.*, Ex. 11 at 9; *compare* 64 FR 13282-83.

Exhibit List
FDA Petition Response
Over-the-Counter Drug Labeling
Docket No. 98N-0337/CP2

Exhibit 1.	September 16, 1999, CHPA Type Size and Exemption Process Memorandum
Exhibit 2.	November 23, 1999, Slide Presentation by R. William Soller, Ph.D., and William Bradley, CHPA, at FDA Feedback Meeting on OTC Label Content and Format
Exhibit 3.	Watanabe, R. K., "The Ability of the Geriatric Population to Read Labels on Over-the-Counter Medication Containers," 65 *Journal of the American Optometric Assoc.* 32 (1994)
Exhibit 4.	Smith, S., "Letter Size and Legibility," 21 *Human Factors* 661 (1979).
Exhibit 5.	July 29, 1992, Letter from William Bradley, CHPA, to William E. Gilbertson, FDA
Exhibit 6.	November 2, 1999, Memorandum and Slide Presentation from CHPA to Charles Ganley, FDA
Exhibit 7.	October 6, 1997, CHPA Comments to Proposed Rule, Appendix H
Exhibit 8.	Cheung, A., et al., "Visual Acuity in Reading Nonprescription Drug labels," *Can. Pharm. J.* 47 (Dec./Jan. 1995).
Exhibit 9.	September 29, 1995, Comments by CHPA, Public Hearing on OTC Labeling, TS10 to FDA Docket No. 95N-0259
Exhibit 10.	August 5, 1991, Comments of the National Consumers League on Print Size and Style of Print for Over-the Counter Drug Products, C57 to FDA Docket No. 90P-0201
Exhibit 11.	June 29, 1999, Slide Presentation by R. William Soller, Ph.D., and William Bradley, CHPA, at FDA Feedback Meeting on OTC Label Content and Format

EXHIBIT 1

Consumer Healthcare Products Association

Representing producers of quality dietary supplements and OTC medicines

Founded 1881

Type Size and the Exemption Process

As an individual holding an interesting position between the industry bench, where I started, and the regulator's desk, I will open with two observations that reflect the hub of the problem now facing us.

One observation is that there is a gap in practical experience between the regulators and regulated, and the regulated are concerned that there is not a better understanding of industry's difficulties with the Final Rule. The concern is amplified by various aspects of the rule, particularly: the level of evidence used to support certain provisions; the assumptions about the extent to which the provisions for type size would affect implementation; and the economic consequences of the packaging changes potentially required by the Rule.

A second observation is that there is a disparity between what is required for new OTC drugs in terms of label comprehension studies on the one hand (recognizing the issue is more content that format, although format has at times played an important role, e.g., for H2 blockers and Minoxidil) and, on the other hand, the notable lack of convincing objective support that 6-point type adds an advantage in legibility over smaller type sizes down to and including 5-point type. I report to you a sense of an unfair double standard.

These are important observations, and it is important to find ways to address them. They are important because they suggest a ripple in what has been up to the Final Rule a fairly reasonable and productive partnership on labeling.

We have additional concerns that relate to columns and questions about exemption process, among others.

First, we are six months from the publication of the Final Rule, and we still do not have an answer on the use of columns – an issue that should have already had an easy, quick and reasonable solution. Companies have had to wait on implementation of the rule, knowing that a favorable solution to the use of columns would mean a dramatic difference in the scope, extent, and cost of implementing the Final Rule. Question: when?

Second, we have been told at our recent feedback meetings on labeling that decisions on answering the issue of columns – and presumably similar issues – must come from above, not from those around the table. Do we have the right people around the table?

Third, the agency stated in a recent Response Letter dated August 23rd -- "because the agency considers 6-point type size as the minimum needed to assist consumers in reading and understanding OTC drug product labeling, it does not intend at this time to grant any exemption from 21CFR 201.66 on a type size below 6-point type." I call your attention to the phrase "at this time." Is FDA's response a jurisdictional reaction supporting an inflexible 6-point type size, or a reasoned response showing willingness, based on appropriate documentation, to use the exemption process judiciously to allow less than 6-point type?

Fourth, as stated above, some of the primary evidence used by FDA to support 6-point type actually provides data showing comparable readability responses for 5-point and 6-point type. Yet, the cost to implement a 6-point type size minimum, versus a 5-point type provision, is massively out of proportion to the very thin ribbon of evidence supporting the 6-point minimum. There is simply no clear objective evidence that a 6-point type size minimum has distinct advantages over somewhat lower type sizes. Why did FDA rely essentially on subjective evidence for the 6-point minimum? Indeed, along these lines, a question we have heard more than once is – why is 4.5-point type acceptable on one set of products (i.e., NLEA-related products), but not on another set (i.e., OTCs) intended for the same set of consumers?

If the division is unwilling or unable to understand our situation, then where does the division suggest we turn to address these very important issues? If the division is willing and able to dialogue, then what specifically does the division need to move forward meaningfully with us on these issues?

R. William Soller, Ph.D.
Senior Vice President and Director of Science & Technology

EXHIBIT 2

Consumer Healthcare Products Association

Representing Producers of Quality Nonprescription Medicines and Dietary Supplements

Founded 1881

November 23, 1999 Feedback Meeting on OTC Label Content and Format: Feedback, Exemptions, and Special Packaging

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

William Bradley
Vice President, Technical Affairs

Revised:11-22-99

Overview

- **Introduction**
  - Feedback to Industry's Requests
  - Elements of the Final Rule Suitable for Exemption
  - Manufacturing Capabilities: ETL
  - Parity Across FDA-regulated Consumer Products
  - Modified vs. Standard Formats
- **Exemption Process**
  - Overview
  - Elements of a Feedback Letter
  - Examples of Typical Exemptions Are Needed
  - Elements of a Feedback Letter: Notification Process
- **Special Packaging**

Introduction:
Feedback to Industry's Requests

- **CHPA's and CTFA's Requests**
  - Use of columns (Draft Guidance dated 11/19/99; received 11/22/99)
  - Light type on a dark background (trade dress)
  - **2-year time extension**

Is is vital that industry have timely and reasonable feedback on these critical issues.

- **Feedback to Company Inquiries**
  - Consistency is needed!

Introduction:
Elements of the Final Rule Suitable for Exemption

- From September 17th Feedback Meeting: Any one element, or a combination of elements, of the Final Rule may be suitable for exemption.
- The omission of one or more elements of the Final Rule is unlikely to be perceived by consumers as seriously affecting a "standard look," particularly when those omissions may:
  - Help enhance the consumer friendliness of the label
  - Even help the appearance of a standard look (I.e., help to keep the labeling on 1-2 panels *vs.* 4 panels).

Introduction
Manufacturing Capabilities: ETL

- **Types of "Extended Text Labeling" (ETL):**
  - Spin Label
  - Accordion Label
  - Book Pages
  - Fold Down Fifth Panel
  - Bubble on a card
  - Fifth Panel

ETL is not an across-the-board easy answer to the problems posed by the Final Rule.

- **Factors**
  - Cost
  - Reduced line speeds (thicker labels)
  - Lack of data showing:
    - Consumer acceptance
    - Consumer understanding
    - Consumer friendliness
  - Limited supplies
  - Lack of experience with shipment (e.g., effect of heat/moisture on adhesive, type integrity etc.)
  - Liability issues re: damage (removal) on the retail shelf
  - Retailer acceptance of unwrapped ETL
  - Reduction in label space (spin label)
  - Non-standard appearance

Introduction:
Parity Across
FDA-Regulated Consumer Products

- **FDA-regulated Consumer Products**
  - OTC Drugs
  - Cosmetics
  - Foods, including dietary supplements
- **Cosmetics, Foods and Dietary Supplements:**
  - Columns
  - Trade Dress
  - 4.5-Point Type Size for Smaller Packages
- **Why not parity for these elements of label formats across all FDA-regulated consumer products?**

Introduction: Parity Across FDA-Regulated Consumer Products

- **Columns**
  - A permitted format element for food nutrition labels *[21CFR 101.91(d),(e),(h),(j)]*
  - Permitted for dietary supplement labels *[21CFR 101.36(e)(11)]*
- **Light Type on Dark Background**
  - Permitted for foods and dietary supplements *[21CFR 101.9(d)(1)(i); 101.36(e)(3)(ii)]*
  - Cosmetic ingredient labeling needs only be "prominent and conspicuous" *[21CFR 701.3(b)]*

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size**
  - 4.5-point type standard for smaller DS packages *[21CFR 101.36(i)]*
    - FDA relied on the CHPA Readability Guidelines as support for this rule *[62Fed. Reg. 49838-9, Sept. 23, 1997]*
  - 4.5-point type is permitted on smaller food labels *[21CFR 101.9(j)]*
  - < 6-point type is permitted on cosmetic ingredient labels *[21CFR 701.3]*

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size**
  - The argument that nutrition labeling or DS labeling is less significant to consumers than OTC labeling is unsupportable.
    - Safety issues are the same: food allergies can be fatal.
  - If 4.5-point type is permitted for food, DS, and cosmetic labeling, then FDA must permit 4.5-point type for OTC labeling.

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size: FDA review of CHPA information**
  - FDA set the 4.5-point type size for dietary supplements in reliance on the CHPA (then NDMA) voluntary label readability guidelines.
    - *"FDA set the minimum type size at 4.5 point in response to the majority of the comments, which stated that this minimum is consistent with the NDMA's Label Readability Guidelines used for over-the-counter drugs (Ref. 4). FDA has received information from NDMA that shows that it did not set this minimum arbitrarily or subjectively, but that it arrived at this minimum type size based on studies of visual acuity and demographics (Ref. 7). FDA has been persuaded by NDMA's data..." [62Fed.Reg. 49830-40, Sept. 23, 1997]*

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size: Evidence-base ...**
  - The primary evidence that FDA cites does not support a 6-point minimum type size.
    - Watanabe study showed little difference in readability between 6.7- and 3.3-point type.
    - NCL study supported less than 6-point type.

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size: Summary**
  - The 6-point minimum type size of the Final Rule conflicts with FDA regulations for food, dietary supplements and cosmetics.
  - The "support" cited for the 6-point type minimum in the Proposed and Final Rules is itself minimal at best.
  - Evidence supports 4.5-point type as readable.

Introduction:
Modified and Standard Formats

"201.66(d) (10) If the title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section, printed in accordance with the specifications in paragraphs (d)(1) through (d)(9) of this section, and any other FDA required information for drug products, and, as appropriate, cosmetic products, other than information required to appear on a principle display panel, requires more than 60 percent of the total surface area available to bear labeling, then the Drug Facts labeling shall be printed in accordance with the specifications set forth in paragraphs (d)(10)(i) through (d)(10)(v) of this section."

- **The Rule does not provide that the Standard Format is more readable than the Modified Format.**
- **The 60:40 calculation is therefore without foundation.**
- **The Modified Format should be able to be used without the 60:40 test.**

Overview

- **Introduction**
  - Feedback to Industry's Requests
  - Elements of the Final Rule Suitable for Exemption
  - Manufacturing Capabilities: ETL
  - Consistency and Fairness Across FDA-regulated Consumer Products
  - Modified vs. Standard Formats
- **Exemption Process**
  - Overview
  - Elements of Feedback
  - Examples of Typical Exemptions That Are Needed
  - Elements of a Feedback Letter: Notification Process
- **Special Packaging**

Exemptions
Overview

- We seek feedback on the general concepts shown by the SKU's that CHPA submitted to FDA.
  - We are not seeking exemptions on the specific SKU's that we submitted on 11/2/99 to FDA.
  - We understand that there might be minor corrections needed to the label text in some cases, but these minor issues are not today's focus.
- We ask for feedback[1] on Modified Format, Voluntary Directions/Warnings and the types of general exemptions that might be considered by companies.

[1] For example: as a Feedback Letter, CPG, Guidance, etc.

See handout/attachment to overheads.

Exemptions
Elements of Feedback

A Use of Modified Format without the 60:40 calculation

B Voluntary directions and warnings may be included in the Drug Facts box when complying with the Final Rule or requesting an exemption for formatting elements of the Final Rule.

C Feedback on Use of Common Exemptions

1 Scope: Any one or combination of elements of the Final Rule may be considered for exemption.

2 Exemption requests maintaining a 6-point body text

3 Exemptions requests for a proportionate reduction in type size of the body text below 6-points but no less than 4.5-point type, consistent with food and cosmetic labeling regulations.

See handout/attachment to overheads.

Exemptions

Label Mockups

Modified Format & Examples of Typical Exemptions

Modified Format: 50:50 Label & Thin Box

- Walgreen's Milk of Magnesia : Current 50:50 Label
- Walgreen's Milk of Magnesia : Standard Format on 50:50 label with run-off
- Walgreen's Milk of Magnesia: Modified Format fits on 50:50 label
- Triaminicin 12's Blister: Standard Format fits on 4 panels -- essentially a 50:50 label
- Triaminicin 12's Blister: Modified Format fits on 2 panels -- essentially a 50:50 label

Size-to-Fit

- Oxy 55's: Current label
- Oxy 55's: Standard format with run-off
- Oxy 55's: Modified format with run-off
- Oxy 55's: Stnd. format with 5.7 body text fits
- Oxy 55's: Mod. format with 5.7 body text fits

"Drug Facts (continued)" vs. Size-to-Fit

- Excedrin 24's Box: Current label
- Excedrin 24's Box: Modified Format with run-off
- Excedrin 24's Box: Modified Format (6-pt type) without without "Drug Facts (continued)" fits
- Excedrin 24's Box: Modified Format and 5.5-point type and "Drug Facts (continued)" fits

"Questions and Comments" outside of DF Box

- Contact 10's Blister: NDA approved label has "Questions and Comments" outside the Drug Facts box

Voluntary Directions.Warnings in Drug Facts Box

- Clear Away Pads: Current label with voluntary directions (diagram)
- Clear Away Pads: Standard format with voluntary directions (diagram)

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Use of Modified Format Without 60/40 Criterion**
  - 50/50 label (Mock-ups)
    - Milk of Magnesia bottle
  - Thin Carton (Mock-ups)
    - Triaminicin
    - Alka-Seltzer Plus Cold
  - **Rationale**
    - The 60/40 criterion is meaningless for packages having equal front and back labels (50/50) or for thin packages where the side panels are minimal.
    - The modified format provides a more standard look than the standard format, if it will fit on fewer panels.
    - The rule itself does not provide that the standard format is more readable than the modified format, so either should be allowed without a 60/40 numerical criterion.

Q

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Reduction in Type Sizes For Small Run-offs**
  - Proportionate Reduction in Type Sizes
    - Oxy Pads
  - Selective Reductions in Type Sizes
    - Nite Time (bottle)
    - Titles/headers to 6-point type, maintaining body text at 6-point and using highlighting (bold face/color) for titles/headers
  - **Rationale:**
    - For support of use of less than 6-point type (see previous overheads).
    - Use of a size-to-fit process
    - Note: proportionate reductions in type size of body text seem preferable to selective reductions, since there are no data to support than one part of essential (i.e., required) labeling is less important than another part of essential labeling.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Omission of "Drug Facts Continued"**
  - Examples:
    - Excedrin 24's (not submitted on November 2nd)
    - Alka-Seltzer Plus Cold
  - **Rationale**:
    - Omission of "Drug Facts Continued" will not affect the "standard look," as the consumer perceives the label, and may help the consumer friendly use of the label by maintaining all elements of the final rule.
    - Arrows, or similarly commonly understood routing icons, can be used to direct the consumer sequentially to different panels.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **"Questions and Comments," Outside the Drug Facts Box**
  - **Examples**
    - Contact Capsules
  - **Rationale:**
    - FDA has approved NDA labeling with the new format, allowing "Questions and Comments" outside the Drug Facts Box.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Use of Voluntary Directions and Warnings in the Drug Facts Box as part of the 60/40 calculation or other common exemptions**
  - The Problem:
    - Situation: A company needs to incorporate voluntary directions (or warnings) into the Drug Facts Label.
    - Problem: FDA has indicated that the company may not use a Modified Format (vs. the Standard Format), since the Standard Format is a fit for the label if the voluntary information is not placed in the Drug Facts Box.
  - The [illegible]ution:
    - [illegible]culations and common exemptions would be undertaken by the company assuming that voluntary directions and warnings are a part of the required information.
    - A exemption would be filed by the company.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Use of Voluntary Directions and Warnings in the Drug Facts Box**
  - Rationale:
    - We recognize that the "Drug Facts Box" is FDA's imprimatur that the information within the Box is FDA approved.
    - Voluntary directions and warnings are not "FDA approved," but they are essential to companies from the standpoint of providing adequate directions for specific dosage forms, for example, and for liability reasons.
    - Voluntary directions and warnings are most logically included within the Drug Facts Box, so that the label information is not disjointed.
    - By not allowing all calculations and common exemptions to be undertaken assuming that voluntary directions and warnings are a part of the required information, FDA will create an unfriendly label (e.g., illogical placement of warnings) and dampen company interest in providing useful information, thereby undermining OTC labeling.

Exemptions

Elements of Feedback

Notification Process

- ✓ Elements of Feedback
- ✓ Examples of Typical Exemption that Are Needed
- Notification Process for These Typical Exemptions:
  - A company may notify FDA that it intends to use any one or more of these types of common exemption requests and submit such notification to FDA with appropriate documentation to demonstrate the need for such an exemption(s). The agency has 14 days to object to the company's notification, and provide reasons for its objection(s). If FDA does not provide written objections within 14 days of submission of receipt of a letter for exemption, the exemption request may be considered approved.

Special Packaging

- FDA needs to provide a flexible approach to small labels (e.g., convenience sizes and travel sizes; other small retail labels) because of the many package configurations.
- Without flexibility on this issue, companies will be faced with unacceptable decisions by FDA, given the what the agency is asking companies to do.

Special Packaging

- **For example, convenience and travel sizes account for 1-2 % of the market.**
  - This means that they are still a significant part of the OTC business ... actually a core business for some companies.
  - This also means that any approach FDA would take in this area would affect a small number of packages relative to the very large number of packages for which the Final Rule is a fit.

Special Packaging

- **Special Packaging**
  - 1-2 dose convenience size
  - Short-term convenience
- **Types of Special Packaging**
  - Bubble on a hang card
  - Tin or plastic of 12's
  - Envelopes
  - Thin cartons
  - 2's foil
  - Rolls, single or blister packed
  - Small bottles
  - Others

Special Packaging

- **Types of approaches**
  - Type size exemption
  - Format exemption
  - Package insert in a tin/plastic, with outer statement directing consumers to read the package insert
  - Dispenser labeling
  - Other

Special Packaging

- **We need additional time on this issue.**
  - The solution to convenience sizes will have a retail trade and manufacture component, since one package type does not fit all class of trade.
  - **Recommendation:** Series of follow-up meetings with FDA.

Conclusion

- **Discussion**
  - Feedback on use of columns and trade dress
  - Common Exemptions
  - Approach to special packaging
  - Feedback on time extension

A 2-year time extension would allow us to develop mutually acceptable solutions to the problematic aspects of the Final Rule.

EXHIBIT 3

The ability of the geriatric population to read labels on over-the-counter medication containers

RONALD K. WATANABE, O.D.

ABSTRACT

Background: A Senior Assembly Proposal was presented to the California Assembly calling for a change in over-the-counter (OTC) medication labeling to make the print more readable. It proposes that a panel of optometrists and ophthalmologists be created to define "readable" print. This proposal came about because a large segment of the 60 years and older population is unable to read the printed material on OTC medication labels.

Methods: This study investigated the effects of vertical letter height and horizontal letter compression on readability. Three labels with lettering of different size and compression were used.

Results and Conclusions: It was found that letter compression significantly affected readability while letter height was less of a factor. Results of this study suggest that the lettering on OTC medication labels should be at least 1.2mm in vertical height, or 20/40 Reduced Snellen (RS) visual acuity level, and should have no more than 40 characters per inch.

KEY WORDS: Geriatrics, over-the-counter medications, readability, letter size, letter compression.

Watanabe RK, Gilbreath MK, Sakamoto CC. The ability of the geriatric population to read labels on over-the-counter medication containers. J Am Optom Assoc 1994; 65:32–37.

Senior Assembly Proposal No. 42 was introduced into the California Assembly on October 16, 1989 to analyze the elderly population's ability to read the fine print on over-the-counter (OTC) medication labels. This legislation proposed to " . . . define 'readable' [type] by establishing standards with which the pharmaceutical industry must comply."[1] Their claim was that the cause of the elderly's difficulty in reading drug labels was due to the small letter size used. The purpose of the proposal was to try to make these labels easier to read for elderly consumers.

Clinical experience suggests that many elderly patients would not be able to accurately read OTC drug labels due to a decrease in visual acuity. Previous studies confirm this clinical impression. Weymouth[2] surveyed 1675 eyes in subjects age 40 and older and found that 92.6 percent of the 55–59 year-old age group maintained Snellen acuities of 20/20 or better. There was then a slow decline to 80.2 percent of the 65–69 age group, and a rapid decline to only 6.1 percent of the 80 and older group. The Framingham Eye Study[3] found a similar decline in visual acuity (VA) with age.

Despite this loss of acuity with age, there are many people older than age 60 who maintain excellent Snellen VA. Apparently, even they are having trouble reading OTC labels. Therefore, type size alone may not be responsible for poor readability. Other factors that may be contributing to this difficulty include letter and line spacing, letter contrast, print and background color, and type style. Prince[4] has shown that interletter spacing has a significant effect on print legibility; the higher the compression, the longer it takes to read print. Flom, et al.,[5] have shown that contour interactions have detrimental effects on visual resolution. Adams, et al.[6] have shown that contrast sensitivity is reduced in older adults even when Snellen VA is normal. Holt, et al.,[7] studied actual OTC labels and challenged the assumption that they are cognitively and physically readable by most consumers. In addition to type size, they assessed the reading levels of various labels but did not perform any subjective testing.

Guidelines have been developed to begin to address the readability problems of printed materials among the geriatric population.[8,9] However, the recommendations were generally for larger materials and suggested 11 to 12 point print. These type sizes are too large to use on small medication bottles and are not feasible from a production standpoint.

The American Optometric Association has recommended that such guidelines be developed specifically for drugs and other products that may be hazardous if misused.[10] As a result, in 1990, the Nonprescription Drug Manufacturers Association produced their Label Readability Guidelines.[11] They addressed several factors affecting label readability including type size, spacing, type style, and contrast. Based on a comprehensive literature search and informal subjective ratings of various labels, they developed recommen-

dations that type size be at least 4.5 points if black letters are printed on white labels. They also recommend that "sufficient space should be allowed between letters, lines, and paragraphs, to allow easy reading," without specifying the amount of spacing.

Our study examined a random sample of elderly adults age 60 and over. We attempted to determine the frequency of subjects in this age group who have difficulty accurately reading OTC medication labels. In addition, we examined the effects of two important label readabillity factors: type size and letter compression. By doing so, we attempted to determine minimum type size and letter compression values that can be used to standardize and improve current medication labels.

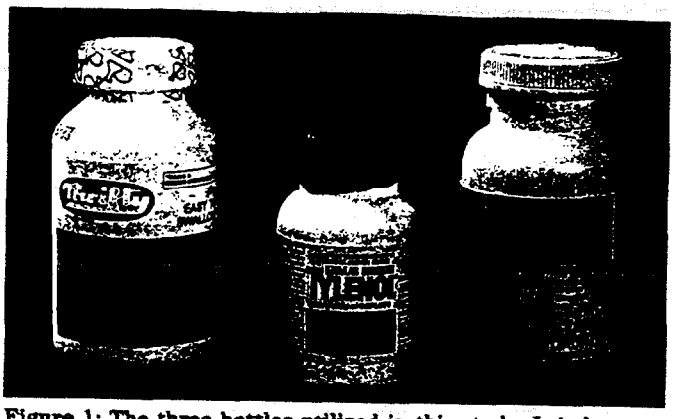

Figure 1: The three bottles utilized in this study. Labels were selected to allow comparisons of letter size and letter compression.

Methods

All of the subjects we surveyed were 60 years of age and older. Patients were selected at random from the Family Practice Service at the Optometric Center of Fullerton and the Veterans Administration Outpatient Clinic in Los Angeles. English was their first language, and all were ambulatory and seen in a clinical setting. They also were in good general health. Finally, the subjects were required to have a near point VA of at least 20/60. The sample size was 92.

Lighting conditions were set to match illuminance levels recommended for visual tasks of small size by the Illuminating Engineer Society (IES) Handbook.[12] Fluorescent room lighting and an auxiliary incandescent lamp were used to provide 75 foot candles (ft cd) of light at the subject's habitual reading position.

The subjects' best corrected near binocular VA was determined with a Bailey-Lovie Word Reading Chart.[13] They were then asked to read a portion of the printed labels from three different drug containers (Fig. 1):

- Advil^{R} (ibuprofen) 200 mg, 100 tablet size container
- Thrifty Maximum Strength Arthritis Relief (aspirin) 500 mg, 60 tablet size container
- Tylenol^{R} (acetaminophen) 325 mg, 50 caplet size container

The print on each container was of high contrast (dark lettering on white labels) and similar font style, but varied in letter size and letter compression. Letter size was determined by measuring vertical height, in mm, of lower case letters, and converting to the equivalent Reduced Snellen (RS) visual acuity level. Letter compression was measured by the Rule of 1000.

Letter compression can be translated into an acuity by counting the number of letters and spaces in one inch and dividing this number into 1000. If the result is greater than the Snellen denominator of the subject's near visual acuity, then he or she should not need any extra magnification or add power to read the material. However, if it is smaller than the Snellen denominator, then the subject may need extra magnification. For example, if there are 25 letters and spaces in one inch, the Snellen fraction denominator is 1000/25, or 40, resulting in a VA level of 20/40. We used this acuity level as an additional way to assess label readability.

By type height, the Advil lettering was 20/40 RS print (approximately 6.7 pt), which was twice as large as the other two at 20/20 RS (3.3 pt)(Table 1). Although the Thrifty and Tylenol lettering were identical in height, they had different degrees of horizontal letter compression, with Thrifty at 20/26 and Tylenol at 20/19. We were therefore able to compare Advil and Thrifty in terms of letter height, and Thrifty and Tylenol in terms of letter compression.

The number of errors was counted and recorded for each label (Table II). If a subject was either unable to finish reading a label or unable to even start reading the label, it was recorded as an asterisk in the charts and tables, and categorized as a very large number of errors for statistical purposes. The two cases were treated identically, since they both indicate that the subject had great difficulty reading the label.

Results

Upon examination of the results, what immediately stands out is the large percentage of the sample population who have habitual near visual acuities worse than 20/20. While one-fourth (23.9 percent) of our subjects had VAs of 20/20 or better, two-thirds (66.3 percent) had VAs between 20/21 and 20/40, and almost 10 percent had VAs worse than 20/40 (Table III). This means that 76.1 percent of our subjects had VAs worse than 20/20. If three-fourths of the 60 and over population cannot read 20/20, yet are given labeling with print that is 20/20

TABLE I: EQUIVALENT REDUCED SNELLEN VISUAL ACUITIES FOR THE THREE LABELS BASED ON VERTICAL HEIGHT AND THE RULE OF 1000

BOTTLE	RS BASED ON VERTICAL HEIGHT	RS BASED ON THE RULE OF 1000
Advil	20/40	20/33
Thrifty	20/20	20/26
Tylenol	20/20	20/19

TABLE II: NUMBER OF SUBJECTS MAKING ERRORS FOR THE THREE LABELS. ASTERISK (*) DENOTES INABILITY TO START OR FINISH A LABEL.

ERRORS	ADVIL	THRIFTY	TYLENOL
0	69	59	24
1	11	15	12
2	6	7	5
3	1	2	4
4	0	2	5
5	0	0	2
6	0	0	0
7	1	0	1
8	1	0	0
9	1	0	1
10	0	1	0
11	0	0	0
12	0	0	0
13	0	0	1
*	2	6	22
TOTALS	92	92	77

TABLE III: NUMBER OF SUBJECTS IN EACH OF THE THREE VA GROUPS. AVERAGE RANKS ARE BASED ON THE NUMBER OF ERRORS MADE BY EACH VA GROUP

VA Group	Number of Subjects	Average Ranks		
		Advil	Thrifty	Tylenol
<20/20	22 (23.9%)	35.0	35.1	24.4
20/21 - 20/40	61 (66.3%)	49.0	47.9	40.3
>20/40	9 (9.8%)	57.4	64.9	66.5

or smaller as in the Tylenol label (20/19 according to the Rule of 1000), it is expected that many of them will not be able to read such a label. We found this to be true, as 28.6 percent of our sample population was not able to read the Tylenol label. This is a very high percentage of our group and suggests that a significant segment of the 60 and over population will not be able to read such labeling.

On the other hand, very few subjects were unable to read the Advil and Thrifty labels (Table II). This result is displayed graphically in Fig. 2. This shows that the Tylenol label is much harder to read than the other two and suggests that such a label utilizes print that requires a visual acuity demand by type height and/or letter compression beyond the ability for a substantial number of the elderly to read accurately.

Visual acuity level correlated with the number of errors that the subjects made. Table III displays the average ranks of the three arbitrary VA groups: 20/20 or better, 20/21 to 20/40, worse than 20/40. The more errors

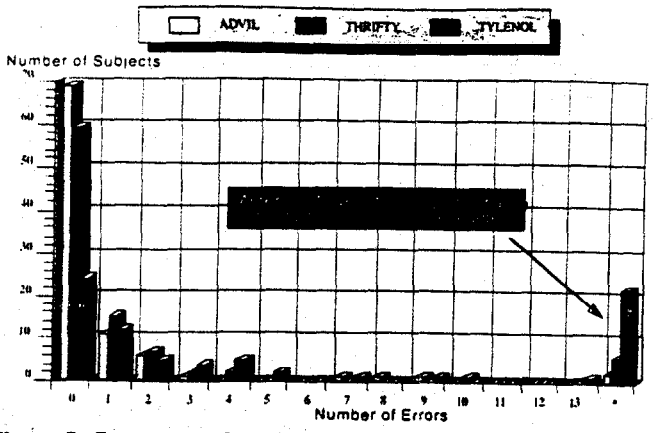

Figure 2: Cumulative data for all three labels. The Advil label had 69 subjects who made no errors, Thrifty had 59, and Tylenol had only 24. Conversely, Tylenol had 22 subjects who were unable to read the label, Thrifty had 6, and Advil had only 2. Data was fairly even for the three labels at the other error values.

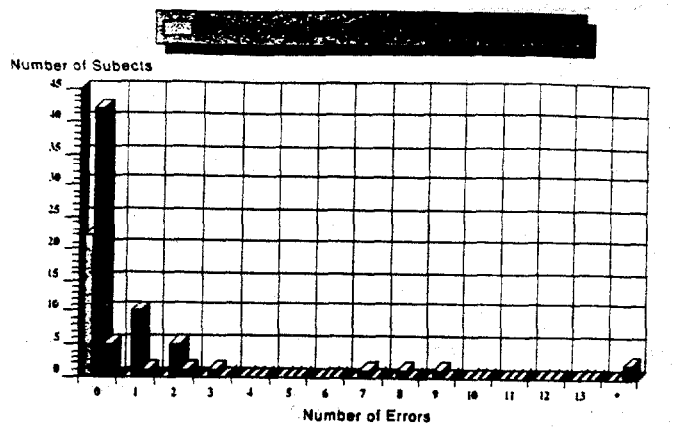

Figure 3: Data for the Advil label, separated by VA groups. Sixty-nine subjects made no errors while reading this label and only 2 were unable to read it.

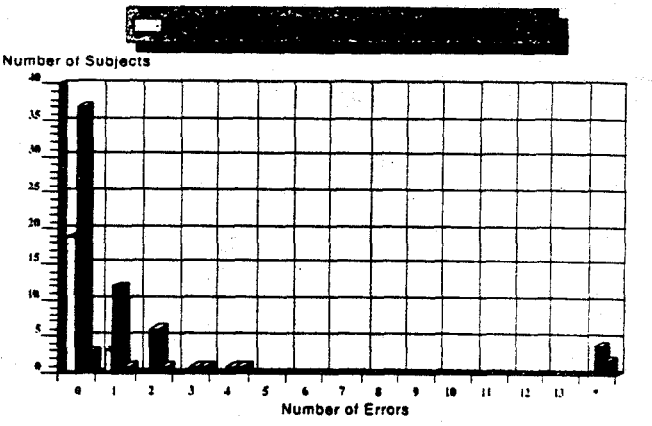

Figure 4: Data for the Thrifty label, separated by VA groups. Fifty-nine subjects made no errors while only six were unable to read it. This is very similar to the Advil data.

made, the higher the rank. As expected, as visual acuity worsened, the number of errors rose.

We next examined the effects of type size on readability. This was determined by comparing the Advil and Thrifty labels (Figs. 3 and 4). A small difference was found in the number of errors made when reading the two bottles, and the Friedman Two-Way ANOVA Test showed that this difference was minimally significant with a P-value of 0.076. In other words, the Advil label was marginally easier to read than the Thrifty label.

Finally, we examined the effects of horizontal letter compression. We were able to do this because the Thrifty and Tylenol labels had the same vertical letter size, but differing degrees of horizontal letter compression. As can be seen (Figs. 4 and 5), there were many more subjects who were unable to read the Tylenol bottle than the Thrifty bottle. The Friedman Two-Way ANOVA Test showed this difference to be significant with a P-value of <0.00005. This basically means that the Tylenol label was much harder to read than the Thrifty label.

Discussion

A high percentage (76 percent) of our sample population of elderly adults demonstrated visual acuities worse than 20/20. We can assume that this decreased acuity is the main reason that many elderly persons are having great difficulty reading nonprescription drug labeling. However, in comparing the effects of type size and letter compression, we found that horizontal letter compression (Thrifty vs. Tylenol) had a greater effect on readability than vertical letter height (Advil vs. Thrifty). This suggests that there is a great degree of sensitivity to small changes in horizontal letter compression, and as a result, letter compression should be a major consideration in defining "readable." According to our comparisons, letter compression approximating the Thrifty print (39 characters per inch) is sufficient to allow good readability. Type height is also an important factor, and although the Advil print was only marginally easier to read statistically, subjective observations by both subjects and researchers indicate that greater effort was expended in reading the smaller Thrifty print. This suggests that letter size approximating the Advil print (20/40 RS or 6.7 pt) should be used.

Although our study examined two major characteristics of the printing on medication labels, we did not exhaust all of the factors that may have affected readability. These other factors include line spacing, letter contrast, print and label background color, and type style. These were beyond the scope of this study but warrant further investigation. "Word wrapping" was another factor that arose during data collection. A number of the subjects remarked that when the print fol-

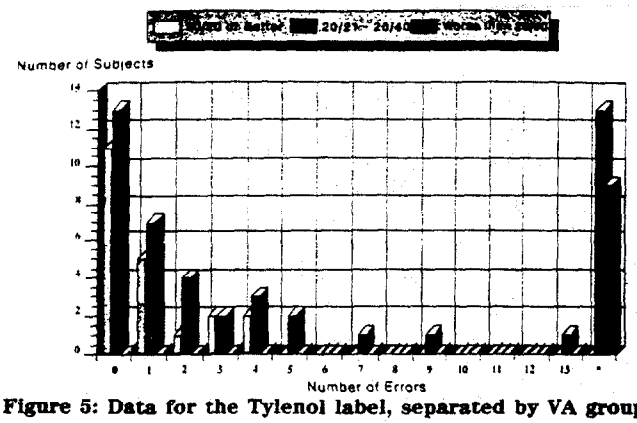

Figure 5: Data for the Tylenol label, separated by VA groups. Only 24 subjects read the label without any errors while 22 were unable to read it at all. This can be compared to Figure 4 to illustrate the effects of letter compression.

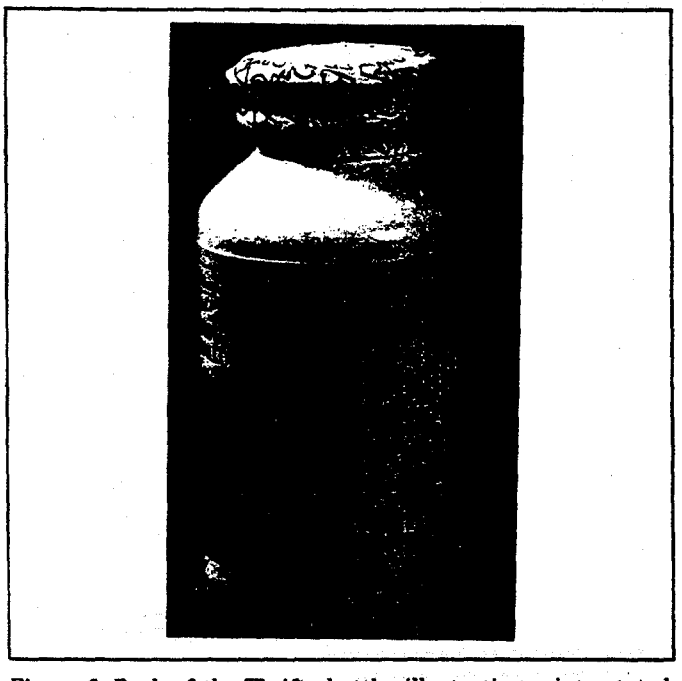

Figure 6: Back of the Thrifty bottle, illustrating print rotated 90°. This eliminates "word-wrapping."

lowed the curvature of the bottle and wrapped around the bottle, they would often lose their place in the text, resulting in poorer comprehension of the material. However, if the lettering was rotated 90° as in the Thrifty bottle so that word wrapping did not occur, reading became subjectively easier (Fig. 6).

We also noted inefficient layout, or use of the surface area, of the Tylenol label and bottle. Figure 7 shows that the label covers only one-half of the bottle. In addition, more than one-third of the label is used for the logo, expiration date, and a picture of two caplets. This means that less than one-third of the bottle is available for directions, warnings and indications for use. It

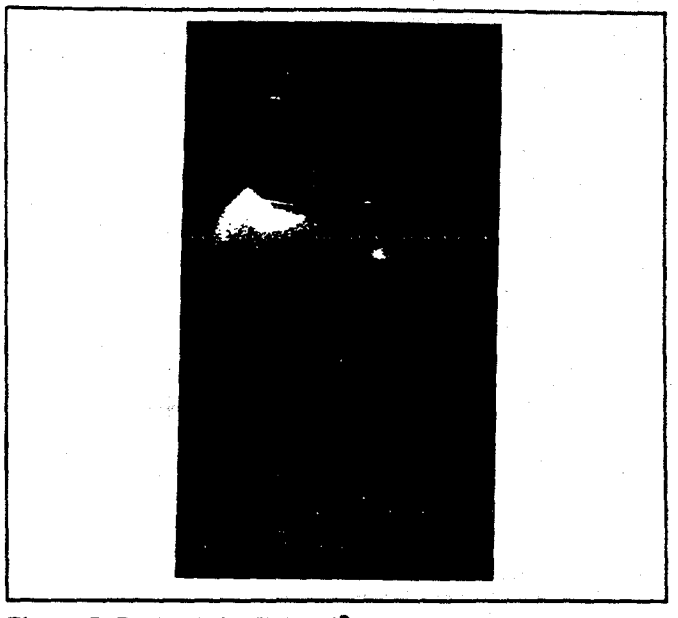

Figure 7: Back of the Tylenol® bottle, demonstrating poor usage of surface area.

is not surprising that this label is by far the hardest of the three to read.

The Advil label has a much more efficient layout. Letter compression is minimal at 30 characters per inch, vertical letter size is large at 20/40 RS, and the bottle is large with a label that covers almost its entire surface area. Moreover, the majority of the label is used for directions, warnings, and indications for use.

Overall, the results of this study have serious implications on the entire geriatric population. Because many elderly individuals cannot accurately read the labeling on OTC labels, and because the elderly tend to use more medications,[10] we can assume that they are at a higher risk of having adverse side effects due to improper usage of these medications. This is due to their known decrease in acuity as compared to the younger population[2,3] and the increase in systemic disease that may be exacerbated by the improper use of these medications.[14] This suggests that standardization of drug labels would greatly benefit the geriatric population.

In conclusion, we found that a significant portion of the elderly population cannot adequately read the print on certain OTC medication labels due in part to small vertical type size and high degrees of horizontal letter compression. Additionally, we discovered that letter compression, not vertical type size, was the more influential factor affecting readability of the labels. Therefore, to maximally enhance readability, we recommend a vertical type size of at least 20/40 RS (6.7 pt) and letter compression of no more than 39 characters per inch for all OTC medication labels. ■

References

1. Senior Assembly Proposal No. 42, Relating to Drugs. California Senior Assembly. Oct. 16, 1989:1–2.
2. Weymouth FW. Effect of age on visual acuity. In: Hirsch MJ, Wick RE, eds. Vision of the Aging Patient. Philadelphia: Chilton, 1960:37–62.
3. Kahn HA, Leibowitz HM, Ganley JP, et al. The Framingham Eye Study: I. Outline and major prevalence findings. Am J Epidemiol 1977 July; 106(1):17–32.
4. Prince JH. The effect of interletter spaces on the legibility of words. In: Prince JH, ed. Studies of visual acuity and reading in relation to letter and word design. Columbus, OH: Institute For Research in Vision, Ohio State University, 1960:121–56.
5. Flom MC, Weymouth FW, Kahneman D. Visual resolution and contour interaction. J Opt Soc Am 1963; 53(9):1026–32.
6. Adams AJ, Wong LS, Wong L, et al. Visual acuity changes with age: some new perspectives. Am J Optom Physiol Optics 1988 May; 65(5):403–6.
7. Holt GA, Hollon JD, Hughes SE, et al. OTC labels: can consumers read and understand them? Am Pharm 1990 Nov; NS30(11):51–4.
8. Boyce MR. Guidelines for printed materials for older adults. Michigan Health Council Health Promotion Project; Oct 1981.
9. Ralph JB. A geriatric visual concern: the need for publishing guidelines. J Am Optom Assoc 1982; 53:43–50.
10. American Optometric Association. The need for guidelines for printed materials for older adults and others with visual impairment. St. Louis: American Optometric Association; Apr 1985.
11. Nonprescription Drug Manufacturers Association. Label Readability Guidelines. Washington, DC: Nonprescription Drug Manufacturers Association; Apr 1990.
12. Illuminance categories and values. IES Lighting Handbook, 1987 Application Volume. New York: Illuminating Engineering Society of North America; 1987; 2–5, 2–8, 2–9.
13. Bailey IL, Lovie JE. The design and use of a new near-vision chart. Am J Optom Physiol Optics 1980; 57:378–87.
14. Rowe JW, Besdine RW. Drug therapy. In: Rowe JW and Besdine RW, eds. Health and Disease in Old Age. Boston: Little, Brown and Company, 1982:39–53.

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EXHIBIT 4

HUMAN FACTORS, 1979, 21(6), 641–670

Letter Size and Legibility[1]

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The legibility of displayed letters depends upon their size, or more accurately, their subtended visual angle at any viewing distance. Current design standards recommend letter heights in the range from 0.003 to 0.007 rad (10 to 24 min of arc) for good viewing conditions, with 0.0015 rad (5 min) considered a lower limit based on normal visual acuity. A field study involving some 2000 measures for over 300 printed displays found a mean letter height of 0.0019 rad (7 min) at the limit of legibility, with over 90% legibility at 0.003 rad and virtually 100% at 0.007 radians.

INTRODUCTION

The literature on legibility has become so extensive that designers of visual displays often rely on simplified standards rather than detailed research data when specifying desired symbol characteristics. The most common displayed symbols are, of course, letters. It seems worthwhile to examine current design standards for letter legibility and assess their practical implications.

A fundamental condition for legibility is contrast in brightness, so that a displayed symbol can be discriminated from its visual background. As a practical matter, adequate contrast is usually achieved: e.g., black letters printed on a white page, bright letters reflecting light from a traffic sign, or luminous letters on the darker background of an electronic display.

Given adequate contrast, a displayed symbol must be large enough so that it can be identified and discriminated from other symbols. How large a letter should be depends on the distance from which it will be viewed. Within the limits of visual accommodation, the closer the display the smaller the letters which can be identified.

Given adequate letter size, other factors influence legibility to a lesser degree: the total array or alphabet of letters used, the detailed features of shape which permit one letter to be distinguished from or confused with another, the use of upper or lower case, the height-to-width ratio, the stroke width, etc.

But it is letter size which most seriously constrains display design. If letters must be made large to ensure legibility, then fewer letters will fit in a fixed display format. What is an adequate letter size? This report discusses that question, and offers some new data to supplement the research already published.

VISUAL ACUITY

Letter legibility is limited by visual acuity. Visual acuity is influenced by many factors, but for normal eyes under normal conditions a "standard acuity" of 1 min of arc is often cited (e.g., Bartley, 1951, p. 959). That is to say, for a fine visual detail to be distinguished it must subtend a visual angle of at least 1 min.

On this basis, in order for us to recognize

[1] Paper first presented at the NATO Conference on Visual Presentation of Information, Het Vennenbos, The Netherlands, September, 1978.

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the significant details of a capital letter "E," its vertical dimension would have to subtend a minimum angle of 5 min, to include its three horizontal strokes and the two spaces between them. A standard visual test using the Snellen Symbol E Chart defines normal acuity as being able to distinguish among differently oriented E's which subtend an angle of 5 min (Grether and Baker, 1972, p. 58).

In practical display applications, however, it is not wise to design to the limits of visual acuity. An engineer will not design a bridge to meet minimum loads, but instead multiplies the strength of supporting trusses by some safety factor so that the bridge can be crossed with greater confidence. A display designer should also include some safety margin, specifying a letter size large enough to be read with confidence. Design standards for visual displays generally recognize the need for a safety margin, and specify letter sizes larger than those at the limits of visual acuity.

DESIGN STANDARDS

In his well-known text, Murrell cites British standards for legibility, and several independent research studies, to recommend that displayed numeral height should be 0.035 inches for each foot of viewing distance (1965, p. 193). Murrell describes this as a "reasonable" size, which makes some allowance for viewers with defective vision. Numerals and letters of this height subtend a visual angle of 10 min, twice the size of those at the defined limit of normal acuity.

This same size, 10 min of arc, is also recommended to display designers by Fletcher (1972) as optimum for "practically error-free readability," without any indication of its source.

Fitts (1951, p. 1293) reported an early design recommendation, from 1892, that printed letters should have a minimum height of 1.5 mm, a figure which still seems valid in light of recent research (e.g., Poulton, 1972). Assuming a normal reading distance of about 330 mm, letters 1.5 mm high subtend a visual angle of 15 min, three times the size at the defined limit of acuity. At arm's length, a reading distance of 460–500 mm, the subtended visual angle would be 10 min.

Gould (1968) has recommended that the minimum character height on electronic displays should subtend a visual angle of at least 12–15 min at normal viewing distances, following earlier recommendations by Shurtleff (1967).

In research reported by Duncan and Konz (1976) viewers were asked to indicate a "preferred" viewing distance from test displays. Numerals which required just 5 min of arc for no-error viewing subtended approximately 23 min when observers had approached the display to their preferred viewing distance. For the eight observers who participated in that study, the ratio of preferred symbol size to smallest legible size varied from 2.1 to 9.5, averaging 4.7 times as large. The authors cite this average ratio as agreeing with a subjective recommendation by Fortuin (1970) that for "easy seeing" objects should be 2.5 times their minimum visible size.

Some design recommendations try to take into account viewing conditions. An example is the formula proposed by Peters and Adams (1959), where required letter height (in inches) for panel labels is specified to be 0.0022 times the viewing distance (in inches), plus a correction factor ranging from 0.06 to 0.26 for differences in illumination level and other reading conditions, plus a second correction factor of 0.075 for important labels. Although this formula is offered with neither theoretical explanation nor support from empirical measures, it has been cited in several editions of a popular human engineering text (e.g., McCormick, 1976, pp. 91-92).

Applying the Peters and Adams formula to

applications involving very long viewing distances (perhaps unjustified since it is intended for panel labels), specified letter sizes could subtend a visual angle as small as 8 min. At close distances, for important labels read under unfavorable viewing conditions, the formula specifies a letter size subtending as much as 90 min of arc, which seems excessive in comparison with other design standards.

In the United States, display designers have for some years been familiar with character size requirements for both letters and numerals established by the Department of Defense, currently expressed in Military Standard 1472B (1974). In Section 5.5.5.12 (page 94) and Table X (page 95) character height for a viewing distance of 710 mm is specified for three kinds of displayed data and two conditions of illumination.

According to this standard, for critical data with variable position on a display, character height should be 3–5 min for a "high" luminance level (at or above 3.4 cd/m²) and 5–7.5 min for lower luminance levels. Critical data with position fixed should be 2.5–5 mm for high luminance, 3.8–7.5 mm for low. Noncritical data (identifying labels, routine instructions, etc.) may be as small as 1.3–5 mm regardless of luminance. The subtended visual angles calculated from these specifications range from 6 to 37 min under the various categorized conditions.

Section 5.5.5.13 (page 94) of this standard specifies character height for "general dial and panel design" with high luminance, for various viewing distances: 2.3 mm at a distance of 510 mm or less; 4.3 mm at 510–910 mm; 8.6 mm at 910 mm to 1.83 m; 17 mm at 1.83–3.66 m; and 29 mm at 3.66–6.10 m. The visual angle implied by this specification varies from 16 min at the far end of each viewing range to 27–33 min at the near end.

Considering the various design recommendations cited above, some differences are apparent. There is also some reassuring consistency, which is most readily discerned when design standards are expressed in terms of visual angle. This point deserves further discussion.

VISUAL ANGLE

Virtually all design standards for display legibility concede, either explicitly or implicitly, the prime importance of subtended visual angle. In the examples cited above, either the standard is specified directly in minutes of arc, or as a constant ratio of character height to viewing distance, which amounts to the same thing. MIL-STD-1472B also specifies use of a constant height-to-distance ratio for translating its recommendations to different viewing distances (1974, footnote to Table X).

Even the formula offered by Peters and Adams (1959) contains a constant ratio in its distance multiplier. The addition of correction factors, however, increases the specified visual angle at shorter viewing distances, and so the formula represents an exception to the rule.

Ignoring this exception, the other design standards cited here share a common assumption, that equal visual angles provide equal legibility. When viewing distance is doubled, then displayed character height must be doubled, too, if legibility is to be maintained.

How valid is this assumption? At very great viewing distances, it is possible there may be some decrease in visual acuity caused by atmospheric attenuation. At very short distances, at the tip of your nose, there is failure of visual accommodation. But over a large range of viewing distances, everyday experience suggests that display legibility can be specified simply in terms of a constant visual angle.

There is some contradictory evidence. Using specialized instruments under labora-

tory conditions, a few investigators have found anomalous results indicating that visual acuity may be lower (i.e., required visual angle somewhat larger) at close viewing distances, less than 1 or 2 m, than for far vision (Luckiesh and Moss, 1933; Giese, 1946; Tulving, 1958). Perhaps this finding could be confirmed for reading tasks under natural viewing conditions.

If visual angle is used for specification of legibility standards, a more convenient way of expressing visual angle is in radians rather than minutes of arc. One minute of arc is about 0.00029 rad. For small angles, the radian measure is identical with the sine or the tangent, and thus is a direct measure of the ratio of character height to viewing distance. This is what the display designer is concerned with.

Table 1 provides a summary of various design recommendations cited earlier, where the specified letter size has been translated in terms of subtended visual angle, expressed both in minutes of arc and in radians. It can be seen that for good viewing conditions, the range varies from 0.0015 rad at the defined limit of normal acuity to a high of 0.007 rad in MIL-STD-1472B. It is somewhere in this range that the display designer must work.

DESIGN RANGE

Notice that the largest specified letter size, subtending a visual angle of 0.007 rad, is about five times larger than the defined acuity limit and thus provides a rather considerable safety margin. This five-fold range of recommended letter size offers the display designer a potentially difficult choice. At the top of the range, if letters are made larger, then fewer can be included in a display of fixed size, or the display must be made correspondingly larger or viewed from a closer distance.

Extreme assumptions concerning letter legibility can have practical implications. Consider a highway sign whose letters are 300 mm high. If the required visual angle for legibility is 0.0015 rad, this sign might be read by

$\frac{300\text{ mm}}{0.0015} = 200$

TABLE 1

Summary of Cited Recommendations for Size of Displayed Letters

	Specified Visual Angle	
	Minutes of Arc	Radians*
"Normal acuity" (Snellen E Chart)	5	0.0015
"Reasonable" size (of numerals) (Murrell, 1965; Fletcher, 1972)	10	0.0029
Electronic Displays (Shurtleff, 1967; Gould, 1968)	12–15	0.0035–0.0044
"Preferred" size (of numerals) (Duncan and Konz, 1976)	23	0.0067
MIL-STD-1472B (1974)		
General labels, good viewing	16+	0.0046+
Noncritical data	6–24	0.0018–0.0070
Critical data, fixed position		
high luminance	12–25	0.0035–0.0072
low luminance	19–37	0.0054–[illegible]
Critical data, variable position		
high luminance	14–25	0.0042–[illegible]
low luminance	25–37	0.0072–0.0107

* Equivalent to the ratio of required letter height to viewing distance

a driver at a distance of 200 m. If 0.007 rad, then drivers would have to approach within 85 m before they could read the sign. The truth presumably lies somewhere in between.

Consider another example. McVey (1973) has offered human factors specialists a rule of thumb for the preparation of visual materials for projection display. He recommends that 35-mm slides be designed to ensure legibility at a viewing distance six times the width of their projected image. (Experience suggests this is a rather conservative recommendation.) Since slide aspect ratio is 2 × 3, this specified viewing distance represents nine times image height.

If a slide were filled with lines of letters, with vertical spacing between lines equal to the letter height, how many lines of letters could be displayed legibly? If the required visual angle for legibility is 0.0015 rad, 37 lines might be legible to viewers. At the safe end of the recommended range, with larger letters subtending 0.007 rad, only eight lines of letters could be displayed.

Within the range of letter size bounded by these two extremes, where should one choose? It can make a considerable difference in the design of display formats and affect the legibility of visual presentations. If one chooses a smaller letter size for more compact display, to what extent will legibility be compromised? More information is needed about the *distribution* of legibility measures under natural viewing conditions.

A FIELD STUDY

Over a period of several years, this question of display legibility was explored by students in a course on human factors in man-machine systems, at the Graduate School of Engineering, Northeastern University. As a research assignment, students were asked to take legibility measurements themselves and compare their results with recommended standards. A total of 88 student researchers participated in this study.

Each student chose his own display materials to be tested. Some chose samples of small newsprint. Some chose samples of lettering from engineering drawings, or letterheads from company stationery. Some chose larger and more colorful samples from magazine advertising. Some students created large labels themselves in order to test over a greater range of letter sizes. Some tested single letters, or random mixtures of letters and numerals. Most tested single words, or running text. Letter font, of course, was variable from one sample to another, along with other details such as stroke width, spacing, etc.

Some students tested just one display sample. Others tested as many as 10 samples. Altogether some 314 different samples were tested. The smallest letters tested were 1 mm high, and the largest 55 mm. The distribution of letter sizes sampled is shown in Figure 1.

Students were encouraged to test several different people in determining the legibility of their display samples. Some students had just one person view their displays, but most students tested more than one viewer. Altogether, 547 viewers participated. Summing over all of the display samples used, and all of the viewers, a total of 2007 legibility measures were recorded in this field study.

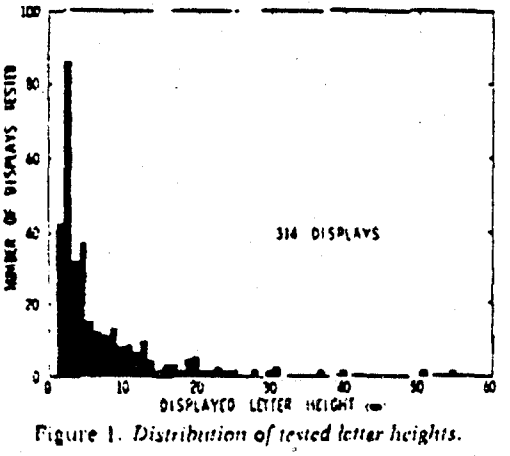

Figure 1. *Distribution of tested letter heights.*

The method used to measure legibility is a simple one. Attach a display sample to a vertical surface. Position a viewer at a distance far enough away so that the display cannot be read. Then ask the viewer to approach slowly, and record the farthest distance at which he/she can read the display. Letter height is then divided by viewing distance to determine the visual angle in radians.

Student researchers submitted the actual display samples used, the recorded viewing distances, and notes on viewing conditions, for an aggregated analysis of results. In that analysis, display letter heights were independently measured to the nearest 0.1 mm, and calculations of subtended visual angles were independently checked. (Because of the mixture of display materials used, letter height was taken to be the height of capitals, when present, or else the height of lower case letters including ascenders or descenders.) Display characteristics and noted viewing conditions were categorized in various ways in the aggregated data analysis, in order to determine whether systematic differences in legibility could be confirmed for factors other than letter size.

This measurement technique, in which viewers approach a fixed display, is a modification of what Tinker (1963, pp. 10-11) calls the "distance method" of determining legibility. It has been used by other investigators (e.g., Weltman and Helgesson, 1972; Duncan and Konz, 1976) and is a method well suited to field study in a natural environment where there is no way to vary physical display size over a continuous range.

Using this technique, the subjective impression of the viewer can be described in a few words. As one approaches a display, there is a far range where it is without question unreadable, then a point where it can *almost* be read, then a step nearer where it *can* be read (this is the point which was measured), and a step or two more where it can be read with ease. Note that in this study there was no attempt to ask viewers to specify a comfortable or preferred viewing distance. The only measure taken was the legibility limit.

This technique obviously does not provide the exact measures of visual angle obtainable in a laboratory, but the rough measures obtained in field research can provide a realistic performance baseline for assessing display legibility under natural viewing conditions.

RESULTS

The smallest visual angle recorded in this study was 0.0005 rad, and the largest was 0.0127 rad. The mean value was 0.0019 and the median 0.0017. The complete distribution of the 2007 measures taken is shown in Figure 2.

This appears to approximate a normal distribution, but is moderately skewed to include some extra observations at larger visual angles. The skewness may be caused by inclusion of viewers with uncorrected visual defects and/or viewers using an unusually strict criterion in deciding at what distance to attempt to read a display.

The most striking feature of this distribu-

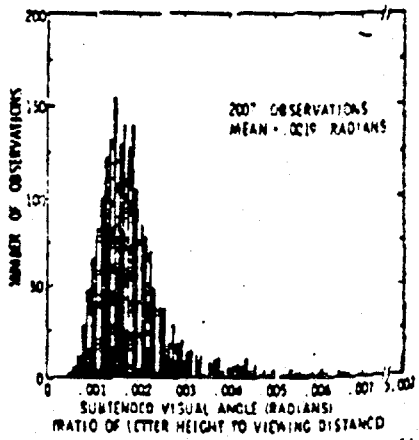

Figure 2. Distribution of visual angle at limit of legibility.

tion is the number of recorded observations in which displays were read at a visual angle below the *postulated lower limit for legibility* of 0.0015 rad (5 min). It seems obvious that letters organized in words are discriminated more easily than the orientation of squarely blocked E's in the Snellen test.

At the other extreme of the recommended range of legibility, it is interesting to note that almost all of the observations in this study recorded a legibility limit at visual angles smaller than the generous size of 0.007 rad specified in military standards. Only eight observations recorded a visual angle larger than 0.007.

To permit a more convenient comparison with design standards, the frequency distribution of observed measures shown in Figure 2 has been replotted as a cumulative distribution in Figure 3. Here, for any visual angle on the abscissa, the corresponding ordinate value indicates the percent of observations in which letters of that size or smaller were legible.

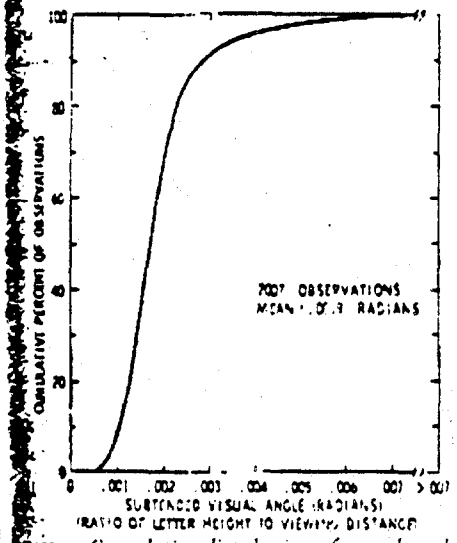

Figure 3. Cumulative distribution of visual angle at limit of legibility.

A cumulative curve of this kind can be a useful predictive tool for display design. This curve indicates, for example, that at the defined limit of normal acuity, at a letter height subtending 0.0015 rad, 38% of displayed letters can be read. At a larger visual angle of 0.0020 rad, 70% of letters are legible. At 0.0028 rad, approximately the size recommended by Murrell (1965), there is 90% legibility. At 0.0046 rad, the minimum label size specified in MIL-STD-1472B, there is 98% legibility.

Doubling letter size from 0.0017 to 0.0035 rad increases legibility from 51 to 94%. Doubling letter size again, from 0.0035 to 0.007 rad, effectively increases legibility to 100%.

On the basis of these numbers, it looks like current design standards do in fact provide realistic guidance, in terms of minimum recommended letter sizes and in the suggested range of sizes. The military standards, in recommending large letters at the high end of the range, seem to include a sizable safety margin, but that is their intent. At the low end of the range, the present results are clearly reassuring, indicating that people can read small letters rather well.

OTHER FACTORS

Measures obtained in this field study were analyzed to examine the effect on legibility of factors other than subtended visual angle. The variety of display samples was so great, and so uncontrolled, that it proved impossible to derive sensible categories based on detailed letter characteristics. However, the general type of displayed material and viewing conditions did seem to make a difference.

Display Material

As noted earlier, most of the display samples were textual in nature, containing either single words or continuous prose. Thus, the general legibility results reported here should be considered applicable only to displays of

word labels. A few of the displays tested, however, did sample other material.

For nine displays containing solely or primarily numerals, such as a list of stock quotations, the mean visual angle for legibility was 0.0021 rad, based on 46 recorded observations. This is slightly larger than the general mean of 0.0019 rad.

For 17 displays containing isolated letters or random letter sequences rather than words, the mean visual angle for legibility was 0.0024 rad, based on 124 observations.

Not too much can be made of discrepant means based on small display subsets, because of uncontrolled variability in the field study, but they do remind one that display context can influence legibility.

Illumination

Most student researchers provided only approximate notes on conditions of illumination, often recording merely a subjective assessment as bright, normal, or dim. Accepting this rough, three-way categorization, the mean legible visual angles were calculated to be 0.0018 for bright illumination, 0.0019 for normal, and 0.0024 for dim.

These mean values are in the expected direction in the sense that letters had to be larger to be read in "dim" light. However, in view of the uncertainty of categorization and the lack of an objective measure, these results should be regarded merely as compatible with rather than an independent confirmation of known illumination effects.

Viewing Distance

Results of the field study were analyzed specifically to determine whether legibility varied with viewing distance. Observations were aggregated by intervals of one meter of recorded viewing distance, and the mean visual angle for legibility was calculated for each interval. As it turned out, the visual angle required for legibility was *not* completely independent of viewing distance.

For observers reading displays from a distance of zero (actually 0.33) to one meter, the mean required visual angle was 0.0030 rad, based on 162 measures, which is about the same as Murrell's recommended reasonable size for reading (see Table 1). For displays read from greater distances, mean visual angle varied from 0.0016 to 0.0023 rad with no consistent pattern evident. The means and ranges of observed values are shown in Table 2. The standard error of individual observations in this study was calculated to be 0.001 rad.

The noteworthy difference here is between the larger visual angles required for legibility at distances less than one meter as compared with greater viewing distances. Evidently, if letters are so small that a viewer has to come close to read them, some viewers must come closer still in order to compensate for loss in visual acuity.

This finding is consonant with the anomalous laboratory results cited earlier. It might be attributable to loss of accommodation (close focusing) in some older viewers. Average age of the student researchers was 30 years. Some were older, of course, and may have chosen other older persons for testing. The student researchers seldom noted the ages of their viewers, however and so this suggested cause is only speculative.

The practical implication is clear enough: letter size on equipment labels and displays intended for close viewing should be somewhat larger in visual angle than on signs to be read at a distance.

CAUTIONARY COMMENTS

The strong dependence of legibility on letter size imposes fundamental constraints on display design. The data reported here confirm that current standards for letter size do provide realistic guidance. For general signing, labels, and printed material, a letter height subtending a visual angle of 0.007 rad is certainly legible, and letters half that size or less can be used with little loss in legibility

TABLE 2

Legibility and Viewing Distance

Viewing Distance (m)	Number of Observations	Mean Legible Visual Angle (rad)	Range of Observations	
			Smallest (rad)	Largest (rad)
0–1	171	0.0030	0.0011	0.0127
1-2	633	0.0018	0.0007	0.0064
2-3	405	0.0016	0.0007	0.0065
3-4	200	0.0019	0.0007	0.0082
4-5	132	0.0021	0.0008	0.0064
5-6	111	0.0023	0.0008	0.0077
6-7	68	0.0021	0.0009	0.0059
7-8	82	0.0017	0.0008	0.0064
8-9	62	0.0019	0.0005	0.0065
9-10	42	0.0019	0.0008	0.0057
10-22	121	0.0018	0.0007	0.0052
Overall	2007	0.0019	0.0005	0.0127

when more compact display formats are required.

The present results, however, will not necessarily apply in special situations, for displays involving unusual letter shapes, or for unusual viewing conditions. Where circumstances are special, then special testing may be needed to determine display legibility. As an example, for older people viewing luminous labels at night, Mourant and Langolf (1976) report that a letter size of at least 0.008 rad ("0.64 cm high at an 81.3-cm viewing distance") is necessary to ensure legibility.

Some other cautionary comments are in order. Legible symbols in themselves do not guarantee effective displays. It can happen, for example, that symbols legible for one purpose may be unreadable for another (Smith, 1978). From the present study, where reading was the task used to measure legibility, extrapolation to situations involving formal display use would seem justified. However, Tinker (1963) argues that measures of visibility or perceptibility at a distance do not necessarily predict speed and comprehension in conventional reading tasks.

Even when displayed symbols are large enough to ensure legibility, other factors can limit display use. Displayed data can be presented in such great amount, or in such difficult formats, that a viewer has difficulty abstracting needed information (Smith, 1963). Words clumsily chosen for signs, labels, and instructions can confuse readers or defy understanding altogether (Chapanis, 1965). Displays may be legible, and well-designed in other respects, and yet be unseen by their intended viewers, or seen but not really noticed, or noticed but soon forgotten (Johansson and Rumar, 1966). Legibility, then, is only the necessary first goal in the design of effective displays.

ACKNOWLEDGMENTS

Sabrah Harper and Ruth Thompson helped with the data analysis. Paul Green made sensible suggestions to improve the report. Stephen Konz provided reference material. The field study participation of student researchers and test observers can only be acknowledged collectively.

REFERENCES

Bartley, S. H. The psychophysiology of vision. In S. S. Stevens (Ed.) *Handbook of experimental psychology*. New York: Wiley, 1951.

Chapanis, A. "Words, words, words." *Human Factors*, 1965, 7(1), 1-17.

Duncan, J. and Konz, S. Legibility of LED and liquid-crystal displays. *Proceedings of the S.I.D.*, 1976, 17(4), 185-186.

Fitts, P. M. Engineering psychology and equipment design. In S. S. Stevens (Ed.) *Handbook of experimental psychology*. New York: Wiley, 1951.

Fletcher, D. Matching operator's eyes with machine displays. *Digital Design*, 1972, 2(11), 42-43.

Fortuin, G. J. Lighting: physiological and psychological aspects. In *Ergonomics and physical environmental factors*. 237-259. Geneva: International Labour Office, 1970.

Giese, W. J. The interrelationship of visual acuity at different distances. *Journal of Applied Psychology*, 1946, *30*, 91-106.

Gould, J. D. Visual factors in the design of computer-controlled CRT displays. *Human Factors*, 1968, *10*(4), 359-376.

Grether, W. F. and Baker, C. A. Visual presentation of information. In H. P. Van Cott and R. G. Kinkade (Eds.) *Human engineering guide to equipment design*. Washington: U.S. Government Printing Office, 1972.

Johansson, G. and Rumar, K. Drivers and road signs: A preliminary investigation of the capacity of car drivers to get information from road signs. *Ergonomics*, 1966, 9, 57-62.

Luckiesh, M. and Moss, F. K. The dependency of visual acuity upon stimulus-distance. *Journal of the Optical Society of America*, 1933, *23*(1), 25-29.

McCormick, E. J. *Human factors in engineering and design*. New York: McGraw-Hill, 1976.

McVey, G. F. Slide legibility. *Human Factors Society Bulletin*, July 1973, *16*(7), 4-5.

MIL-STD-1472B Human engineering design criteria for military systems, equipment and facilities. Washington, D.C.: U.S. Department of Defense, 31 December 1974.

Mourant, R. R. and Langolf, G. D. Luminance specifications for automobile instrument panels. *Human Factors*, 1976, *18*(1), 71-83.

Murrell, K. F. H. *Ergonomics*. London: Chapman and Hall, 1965.

Peters, G. A. and Adams, B. B. Three criteria for readable panel markings. *Product Engineering*, 1959, *30*(21), 55-57.

Poulton, E. C. Size, style, and vertical spacing in the legibility of small typefaces. *Journal of Applied Psychology*, 1972, *56*(2), 156-161.

Shurtleff, D. A. Studies in television legibility—a review of the literature. *Information Display*, 1967, *4*(1), 40-45.

Smith, S. L. Man-computer information transfer. In J. H. Howard (Ed.) *Electronic information display systems*. Washington, D.C.: Spartan Books, 1963.

Smith, S. L. The limited readability of Landolt numerals. *Human Factors*, 1978, *20*(1), 57-64.

Tinker, M. A. *Legibility of print*. Ames, Iowa: Iowa State University Press, 1963.

Tulving, E. The relation of visual acuity to convergence and accommodation. *Journal of Experimental Psychology*, 1958, *55*(6), 530-536.

Weltman, G. and Helgesson, U. Automated testing in commercial graphics design. *Proceedings of the 16th Annual Meeting of the Human Factors Society*, 1972, 207-213.

EXHIBIT 5

Founded 1881

NDMA

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

Better Health
Through Responsible
Self-Medication

July 29, 1992

William E. Gilbertson, Pharm.D. (HFD-210)
Director, Monograph Review Staff
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: [Docket No. 90P-0201]
Print Size and Style of Labeling for Over-the-Counter Drug Products
Notice of Request for Comments [Federal Register, March 6, 1991]

Dear Dr. Gilbertson:

These supplemental comments are submitted on behalf of the Nonprescription Drug Manufacturers Association (NDMA), a 111-year-old trade association representing manufacturers of nonprescription or over-the-counter (OTC) drugs. They are offered in response to the agency's request for comments, published in the Federal Register on March 6, 1991 [56FR 9363], on a citizen petition filed by Pharmacists Planning Service, Inc., requesting regulatory standards for the print of over-the-counter drug product labeling in order to maximize readability and legibility for persons with impaired or deteriorating vision.

I. Executive Summary

As we commented previously (August 5, 1991), NDMA has adopted Label Readability Guidelines developed through a comprehensive assessment of the world literature on readability. These Guidelines have been distributed as part of a voluntary program by the industry to enhance the readability of OTC drug labeling. Copies have been provided to the agency to furnish to prospective commentors on request.

NDMA is aware that, although there has been general agreement on the quality and value of the Readabiity Guidelines, some commentors have suggested that the recommended minimum type size of 4½ points is too small, and that even those with normal vision have difficulty reading print of that size. These supplementary comments are offered to address that issue.

NDMA concludes that the NDMA guideline of not less than 4½ point type, which can be read by those with 20/55 vision or better, is supported by standard visual acuity definitions and demographic data, as well as in the literature.

NDMA recommends that, if the agency determines it should proceed with standards for readability of OTC labeling, it endorse the carefully developed NDMA Label Readability Guidelines and encourage their implementation by the entire OTC industry.

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Sufi

II. Rationale

In developing the recommended minimum type size for the Guidelines, the NDMA Special Task Force on Label Readability relied on a study by Smith[1], who demonstrated that 98% of the test subjects could read copy that subtended a visual angle of 0.0046 radians. This corresponds to a letter height of 0.06 inches at a viewing distance of 13 inches, normally considered a standard distance for reading. Smith used radians, rather than degrees or minutes of an arc, because of the ease in calculating:

$$\text{radians} = \text{letter height/distance.}$$

For conversion purposes, one minute of an arc is equal to approximately 0.00029 radians. (A circle contains 360 degrees, or 21,600 minutes, or 2π radians. $2\pi/21{,}600 = 0.00029$.)

The official definition of 20/20 vision is the ability to read letters that cover a subtended viewing angle of 5 minutes of an arc[2]. This is equivalent to approximately 0.001454 radians.

At a distance of 13 inches (330 mm), a person with 20/20 vision can read print that is 0.019 inches or 0.48 mm high. This would subtend a viewing angle of 5 minutes of an arc. Other visual acuities are proportional, i.e., a person with 20/40 vision can read print that subtends a visual angle of 10 minutes of an arc (0.0029 radians), and is 0.037 inches or 0.96 mm high. A person with 20/50 vision can read print that subtends a visual angle of 12.5 minutes of an arc (0.0036 radians), and is 0.047 inches or 1.20 mm high, etc.

In type measure, there are 72 points in an inch[3]. Therefore, 4½ points equal (by definition) 0.0625 inches, or 1.59 mm. The subtended visual angle of this size print at a distance of 13 inches is 0.0048 radians, or 16.5 minutes of an arc. If the letters were this high, a person with 20/66 vision would be able to read them at a distance of 13 inches.

The point size of type is not a measure of the height of the capital letters, but the total height from the bottom of the lowest letter (descender) to the top of the highest letter (ascender). The height of the capital letters in 4½ point type is therefore not 0.0625 inches, but usually a little over 3 points, or about 0.042 inches. A capital letter would thus subtend a visual angle of 11 minutes of an arc at a distance of 13 inches, and a person with 20/44 vision, by definition, would be able to read it.

The optical charts used for measuring visual acuity consist of single capital letters. As a practical matter, Smith's study[1] showed that words are easier to read than single letters. In fact, the average subtended angle needed to read words was only 0.0019 radians, compared to 0.0024 radians needed to read single letters, a ratio of 4:5.

According to Smith's study, therefore, words printed in a size of 0.042 inches (the usual size of the capital letters in 4½ point type) would be as easy to read as single letters 0.053 inches high. Letters 0.053 inches high would subtend an angle of 13.9 minutes of an arc at 13 inches, and a person with 20/55 vision would be expected to be able to read them.

This conclusion is consistent with Smith's finding that 98% of his test subjects could read 4½ point type at a distance of 13 inches. It is supported by Holt[4], who tested the readability of OTC labels. He concluded that "the majority of labels [tested] required approximately a 20/50 visual acuity at a reading distance of 16 inches." Data from a 1972 National Health Survey conducted by the U.S. Department of Health, Education, and Welfare[5] also supports this conclusion, showing that only 1.6% of individuals between ages 4 and 74 had vision that was 20/50 or less.

The National Center for Health Statistics[6] uses visual acuity of 20/50 as a cutoff for determining whether a person's vision has been seriously impaired. This would imply that those with 20/50 vision or better are the ones we would expect to be trying to read labels without help. The conclusions are summarized in the following table.

4½ point Type Can Be Read by Those with 20/55 Vision

Visual Acuity	Subtended Angle of an Arc	Reading Distance	Print Height of Capital Letter	Type Point Size
20/20*	5 min.	13 inches	0.48 mm (0.019 in.)	1.7 pt.
20/40	10 min.	13 inches	0.96 mm (0.038 in.)	3.3 pt.
20/50	12.5 min.	13 inches	1.20 mm (0.048 in.)	4.1 pt.
20/55	13.75 min.	13 inches	1.32 mm (0.052 in.)	4.5 pt.

* The official definition of 20/20 vision is the ability to read letters that cover a subtended viewing angle of 5 minutes of an arc

Therefore, the NDMA guideline of not less than 4½ point type, which can be read by those with 20/55 vision or better, is supported by standard visual acuity definitions and demographic data, as well as in the literature.

It must be remembered that print size is but one of many technical factors affecting readability. While 4½ point type *per se* can be read by the vast majority of people,

readability can be obscured by a poor choice of layout, contrast, type style, or other factors. The NDMA guidelines cover **all** of the factors identifies as affecting readability, and stress that the final judgement on readability cannot be made according to a mathematical formula, but must be made by the human eye. It is this final evaluation that determines overall readability of any given label.

NDMA recognizes that labeling cannot be made ideally readable for all individuals. There are conflicting needs for considerable information on OTC packages, and small package sizes. There are individuals with serious vision impairments that have difficulty reading. There are those who are functionally illiterate. There are those for whom English is only a second language.

Against all this, the NDMA Label Readability Guidelines represent the best and most comprehensive compilation of factors that can affect readability, and will result in an overall enhancement of readability for the vast majority of American consumers. NDMA recommends that, if the agency determines it should proceed with standards for readability of OTC labeling, it endorse the carefully developed NDMA Label Readability Guidelines and encourage their implementation by the entire OTC industry.

Sincerely,

William W. Bradley
Director of Technical Affairs

cc. Dockets Management Branch (HFA-305) -- (4 copies)
Paula M. Botstein, M.D. (HFD-101) -- (without references)

WB/mc 7/28/92

REFERENCES

1. Smith, Sidney L., "Letter Size and Legibility," *Human Factors,* 1979, 21(6), 661-670.

2. Davidson, David W., "Visual Acuity" in J. Eskridge, J. Amos, J. Bartlett, *Clinical Procedures in Optometry.* J.B. Lippincott, 1991.

3. *Graphics Master*, 3rd Edition, Los Angeles: Dean Lem Associates, Inc., 1983.

4. Holt, Gary A., et al., "OTC Labels: Can Consumers Read and Understand Them?", *American Pharmacy*, November, 1990, 51-54.

5. Refraction Status and Motility Defects of Persons 4-74 Years: United States, 1971-1972. Data from the National Health Survey, Series 11, No. 206, U.S. Department of Health, Education, and Welfare, National Center for Health Statistics, August, 1978. DHEW Publication No. (PHS) 78-1654.

6. "Eye Conditions and Related Need for Medical Care Among Persons 1-74 Years of Age: United States, 1971-72," National Center for Health Statistics, Series 11, No. 228, 1983.

EXHIBIT 6

CHPA
FOUNDED 1881

Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Formerly Nonprescription Drug Manufacturers Association

Date: November 2, 1999

To: Charles Ganley, M.D., Director, Division of Over-the-Counter Drug Products

From: R. William Soller, Ph.D., Senior Vice President and Director of Science & Technology

Re: Meeting materials for November 23, 1999 Feedback Meeting on Final Rule for OTC Labeling

Attached are the following meeting materials for the November 23, 1999 meeting on the Final Rule for OTC Labeling:

A Hard copy of the overhead transparencies for CHPA's oral presentation
B List of mockup labels supporting the oral presentation

These materials will be provided to FDA on November 2, 1999, during a meeting scheduled for 11:45 am at 9201 Corporate Blvd. At the meeting we will also provide the mockup labels that accompany our oral presentation.

Attachments: As stated

WS/jkq

A

Consumer Healthcare Products Association

Representing Producers of Quality Nonprescription Medicines and Dietary Supplements

Founded 1881

November 23, 1999 Feedback Meeting on OTC Label Content and Format: Feedback, Exemptions, and Special Packaging

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

William Bradley
Vice President, Technical Affairs

Revised:11-02-99

Overview

- Introduction
  - Feedback on Columns, Trade Dress, Time Extension
  - Purpose of the Final Rule
  - The Need for Consistency and Fairness Across FDA-regulated Consumer Products
- Type Size
- Exemption Process
  - Model Exemptions
- Special Packaging

Status of Feedback

- Columns
- Trade Dress
- CHPA Citizen's Petition for a 2 year extension in the implementation date

Is is vital that industry have timely and reasonable feedback on these critical issues

Purpose of the Final Rule

- "This final rule is intended to assist consumers in reading and understanding OTC drug product labeling so that consumers may use these products safely and effectively." Over-the-counter Human Drugs; Labeling Requirements: Final Rule, *Federal Register*, March 17, 1999, p. 13254.
- The purpose is readability.

Purpose of the Final Rule

- The omission of one or more elements of the Final Rule is unlikely to be perceived by consumers as seriously affecting a "standard look," particularly when those omissions may:
  - Help enhance the consumer friendliness of the label
  - Even help the appearance of a standard look (I.e., help to keep the labeling on 1-2 panels *vs.* 4 panels).

Purpose of the Final Rule
A Note on Extended Text Labels

- Types:
  - Spin Label
  - Accordion Label
  - Book Pages
  - Fold Down Fifth Panel
  - Bubble on a card
  - Fifth Panel

- Factors
  - Cost
  - Reduced line speeds (thicker labels)
  - Lack of data showing:
    - Consumer acceptance
    - Consumer understanding
    - Consumer friendliness
  - Limited supplies
  - Lack of experience with shipment (e.g., effect of heat/moisture on adhesive, type integrity etc.)
  - Liability issues re: damage (removal) on the retail shelf
  - Retailer acceptance of unwrapped ETL
  - Reduction in label space (spin label)
  - Non-standard appearance

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **FDA-regulated Consumer Products**
  - OTC Drugs
  - Cosmetics
  - Foods, including dietary supplements
- **Same Health Issues – i.e., Self Care**
  - E.g., food information to avoid food allergies
- **Why Not Consistency in Graphics !**
  - Columns
  - Trade Dress
  - Type Size

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **For Foods and Dietary Supplements, FDA allows:**
  - Columns
  - Light on dark type
  - 4.5-point type for smaller packages
- **For Cosmetics, FDA allows:**
  - Light-on-dark printing for cosmetic labels
  - 4.5-point type

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **Columns**
  - A preferred format element for food nutrition labels *[21CFR 101.91(d),(e),(h),(j)]*
  - Permitted for dietary supplement labels *[21CFR 101.36(e)(11)]*
- **Light on Dark**
  - Permitted for foods and dietary supplements *[21CFR 101.9(d)(1)(i); 101.36(e)(3)(ii)]*
  - Cosmetic ingredient labeling needs only be "prominent and *conspicuous [21CFR 701.3(b)]*

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **Type Size**
  - 4.5-point type standard for smaller DS packages *[21CFR 101.36(i)]*
    - FDA relied on the CHPA Readability Guidelines as support for this rule *[62Fed. Reg. 49838-9, Sept. 23, 1997]*
  - 4.5-point type is permitted on smaller food labels *[21CFR 101.9(j)]*
  - 4.5-point type is permitted on cosmetic ingredient labels *[21CFR 701.3]*

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **Type Size**
  - The 6-point minimum type size of the Final Rule conflicts with FDA regulations for food, dietary supplements and cosmetics.
  - The "support" cited for the 6-point type minimum in the Proposed and Final Rules is itself minimal at best.
  - Evidence supports 4.5-point type as readable.

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **Type Size**
  - The argument that nutrition labeling or DS labeling is less significant to consumers than OTC labeling is unsupportable.
    - Safety issues are the same: food allergies can be fatal.
  - If 4.5-point type is permitted for food, DS, and cosmetic labeling, then FDA must permit 4.5-point type for OTC labeling.

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **Type Size**
  - FDA set the 4.5-point type size for dietary supplements in reliance on the CHPA (then NDMA) voluntary label readability guidelines.
    - *"FDA set the minimum type size at 4.5 point in response to the majority of the comments, which stated that this minimum is consistent with the NDMA's Label Readability Guidelines used for over-the-counter drugs (Ref. 4). FDA has received information from NDMA that shows that it did not set this minimum arbitrarily or subjectively, but that it arrived at this minimum type size based on studies of visual acuity and demographics (Ref. 7). FDA has been persuaded by NDMA's data..." [62Fed.Reg. 49830-40, Sept. 23, 1997]*

The Need for Consistency and Fairness Across FDA Regulated Consumer Products

- **Type Size**
  - 4.5-Point Type Is Readable.
    - FDA's argument for 6-point type is based on subjective opinion.
    - The primary evidence FDA cites is weak:
      - Watanabe study showed little difference in readability between 6.7- and 3.3-point type.
      - 4.5-point type is readable
        - » Smith: 98% of test subjects could read 4.5-point type at a distance of 13 inches.

Exemptions
Overview

- **A stated approach to exemptions is needed, such that:**
  - When utilizing the available space for labeling, larger type sizes would be used, where possible, but type sizes no smaller than 4.5-point type would be permitted, consistent with the food label, the DS label, the cosmetic label, and the CHPA readability guidelines.
- **5 types of common exemptions are needed.**

Exemptions

- **5 Types of Common Exemptions Are Needed.**
  1. Use of modified format without 60/40 criterion
     - 50/50 label
     - Thin cartons
  2. Omission of "Drug Facts Continued"
  3. Reduction in Type Sizes For Small Run-offs
     - Proportionate Reduction in Type Sizes
     - Selective Reductions in Type Sizes
  4. "Questions and Comments," Outside the Drug Facts Box
  5. Use of voluntary directions and warnings in the Drug Facts Box, as part of the 60/40 calculation or other common exemptions

Exemptions

1 Use of Modified Format Without 60/40 Criterion

- 50/50 label (Mock-up)
  - Milk of Magnesia bottle
- Thin Cartons (Mock-ups)
  - Triaminicin
  - Alka-Seltzer Plus Cold
- **Rationale**
  - The 60/40 criterion is meaningless for packages having equal front and back labels (50/50) or for thin packages where the side panels are minimal.
  - The modified format provides a more standard look than the standard format, if it will fit on fewer panels.
  - The rule itself does not provide that the standard format is more readable than the modified format, so either should be allowed without a 60/40 numerical criterion.

Exemptions

2 Omission of "Drug Facts Continued"

- Examples (Mock-ups)
  - Triaminicin
  - Alka-Seltzer Plus Cold
- **Rationale:**
  - Omission of Drug Facts Continued will not affect the "standard look," as the consumer perceives the label, and will help the consumer friendly use of the label by maintaining all elements of the final rule.
  - Arrows, or similarly commonly understood routing icons, can be used to direct the consumer sequentially to different panels.

Exemptions

3 **Reduction in Type Sizes For Small Run-offs**

- Proportionate Reduction in Type Sizes (Mock-up)
  - Oxy Pads
- Selective Reductions in Type Sizes (Mock-up)
  - Nite Time 10 oz
- **Rationale:**
  - E.g., use 6-point type for active(s), purpose(s), use(s), warnings, directions, and less than 6-point type for the remainder of the required information.
  - For support of use of less than 6-point type (see previous overheads).
  - A slight reduction in type size creates a label that fits, is easily readable, and maintains a standard look.

Exemptions

4 **"Questions and Comments," Outside the Drug Facts Box**

- **Examples (Mock-up)**
  - Contac 10s
- **Rationale:**
  - FDA has approved NDA labeling with the new format, allowing "Questions and Comments" outside the Drug Facts Box.

Exemptions

5 **Use of Voluntary Directions and Warnings in the Drug Facts Box as part of the 60/40 calculation or other common exemptions**

– The Problem:

- Situation: A company needs to incorporate voluntary directions (or warnings) into the Drug Facts Label
- Problem: FDA has indicated that the company may not use a Modified Format (vs. the Standard Format), since the Standard Format is a fit for the label, if the voluntary information is not placed in the Drug Facts Box.

– The Solution: (E.g., Dr. Scholl's Clear Away; Oxy Pads)

- All calculations and common exemptions would be undertaken by the company assuming that voluntary directions and warnings are a part of the required information.
- A exemption would be filed by the company.

Exemptions

5 **Use of Voluntary Directions and Warnings in the Drug Facts Box**

- FDA maintains that the "Drug Facts Box" is FDA's imprimatur that the information within the Box is FDA approved.
- Voluntary directions and warnings are not "FDA approved," but they are essential to providing adequate directions for specific dosage forms, for example, and for liability reasons.
- Voluntary directions and warnings are truthful & nonmisleading and are logically included within the Drug Facts Box, so that the label information is not disjointed.
- By not allowing all calculations and common exemptions to be undertaken assuming that voluntary directions and warnings are a part of the required information, FDA will create an unfriendly label (e.g., illogical placement of warnings) and dampen company interest in providing truthful & useful information, thereby undermining OTC labeling.

Exemptions

✓ **5 types of common exemptions are needed.**

→ **An approach to exemptions is needed, such that:**

- When utilizing the available space for labeling, larger type would be used, where possible, but type sizes no smaller than 4.5-point type would be permitted, consistent with the food label, the DS label, and the cosmetic label and the CHPA readability guidelines.

Special Packaging

- FDA needs to provide a flexible approach to small labels (e.g., convenience sizes and travel sizes; other small retail labels) because of the many package configurations.
- Without flexibility on this issue, companies will be faced with unacceptable decisions by FDA , given the what the agency is asking companies to do.

Special Packaging

- **For example: convenience and travel sizes account for 1-2 % of the market.**
  - This means that they are still a significant part of the OTC business … actually a core business for some companies.
  - This also means that any approach FDA would take in this area would affect a smaller number of OTC drug packages relative to the larger number of packages for which the Final Rule is a fit.

Special Packaging

- **Special Packaging**
  - 1-2 dose professional sample
  - 1-2 dose convenience size
  - Short-term convenience
- **Types of Special Packaging**
  - Bubble on a hang card
  - Tin or plastic of 12's
  - Envelopes
  - Thin cartons
  - 2's foil
  - Rolls, single or blister packed
  - Small bottles
  - Others

Special Packaging

- **Types of approaches**
  - Type size exemption
  - Format exemption
  - Package insert in a tin/plastic, with outer statement directing consumers to read the package insert
  - Dispenser labeling
  - Other

Special Packaging

- **We need additional time on this issue.**
  - We need answers from FDA -- and we need to assess those answers -- on other aspects of the Final Rule, per this submission (and others we have made).
  - The solution to convenience sizes will have a retail trade and manufacture component, since one package type does not fit all classes of trade.
  - **Recommendation:** Series of follow-up meetings with FDA.

Conclusion

- **Discussion**
  - Feedback on use of columns and trade dress
  - Feedback on the requested common exemptions
  - Approach to special packaging

Consumer Healthcare Products Association

Label Mockups Illustrating the Value of Flexibility In the OTC Labeling Rule

#	Product, SKU	Type Sizes Used	Description
1	Milk of Magnesia 26 oz.	"Drug Facts" – 10 points Headings – 8 points Subheadings – 7 points Body text – 6 points	This has a 50/50, front/back label, where the 60/40 rule does not logically apply, nor does it allow the modified format. The standard format does not fit. The modified format fits, however, with, 6 pt. body type.
2	Alka-Seltzer Plus Liqui-Gels 12s	"Drug Facts" – 14 points Headings – 9 points Subheadings – 6 points Body text – 6 points	Thin box, with side panels too thin to bear major body text. Essentially, therefore, this is like a 50/50 label, and the 60/40 calculation does not logically apply, because it would involve use of the PDP for informational labeling, and would interfere with trade dress. The standard format does not fit. The standard format, however, fits on 4 panels in 6 pt. type if "Drug Facts (continued)" is omitted.
3	Trian[illegible] 12s	"Drug Facts" – 8 points Headings – 6½ points Subheadings – 6 points Body text – 6 points	Thin box, 60/40 rule does not work to allow modified format. Standard format does not fit, even on 4 panels. Modified format fits on 2 panels, with 6 pt. body type, if "Drug Facts (continued)" is omitted.
4	Oxy 55s	"Drug Facts" – 7 points Headings – 6.8 points Subheadings – 5.7 points Body text – 5.7 points	Neither standard nor modified formats fit with 6 pt. body type. Both standard and modified formats fit if type size is slightly reduced to 5.7 pt.
5	Nite Time 10 oz.	"Drug Facts" – 9 points Headings – 7 points Subheadings – 6 points Body text – 6 points through "Directions," 5 points thereafter	Modified format does not fit with 6 pt. type throughout. Modified format fits on 2 panels with mixed type sizes. The body text is 6 pt. type through "Directions," and 5 pt. type after "Directions."
6	Contac 10s	"Drug Facts" – 9 points Headings – 8 points Subheadings – 6 points Body text – 6 points	Standard format does not fit as written. Standard format fits on 1 panel, however, in 6 pt. body type, if "Comments or Questions" is moved outside the box.
7	Dr. Scholl's Clear Away 16s	"Drug Facts" – 9 points Headings – 8 points Subheadings – 6 points Body text – 6 points	Standard format fits. This example shows voluntary directions (diagram) included within "Drug Facts" box.

EXHIBIT 7

H

Nonprescription Drug Manufacturers Association

FDA'S OTC DRUG LABELING PROPOSAL

JUSTIFICATION FOR NDMA'S RECOMMENDATION FOR LESS-THAN-6 POINT TYPE

NDMA agrees that the type size on OTC product information panels should be as large as practicable, based upon the space available for the labeling and the amount of information required on the product. In general, larger print is easier to read, especially in poor light, or by the elderly, who need more light to read a given presentation of information.

While 6-point type is a good target for labeling, and one which NDMA's own Label Readability Guidelines recommend, it is not possible to fit the amount of information required, in 6-point type, on an estimated 20-25% of OTC product labels. This, however, should not be necessary, since smaller than 6-point type can be readily readable, as found by the NDMA Task Force on Label Readability, and as is recognized in other labeling regulations.

The NDMA Task Force found that a **minimum** type size of **4.5 points** for readability is supported by (1) the definition of visual acuity, (2) studies of visual acuity, (3) demographic data, and (4) the literature.

(1) The definition of visual acuity is based on the ability to read letters of a given size at a given distance. A person with 20/20 vision can read letters 0.019 inches high at a distance of 13 inches. Other visual acuities are proportional. **By definition**, a person with 20/44 vision can read 4½ point (1/16 inch high) letters at the same distance.

(2) The Framingham eye study[1] found that 98.5% of the population, and 95% of those aged 75-84, had visual acuities of 20/50 or better (best eye corrected).

(3) The National Center for Health Statistics uses visual acuity of 20/50 to determine whether a person's vision is seriously impaired. Those with worse than 20/50 vision should have help in reading.

(4) A study by Smith[2] demonstrated that 98% of the test subjects could read the equivalent of 4½ point type at a distance of 13 inches, confirming the definition of visual acuity in (1) above.

The validity of 4.5-point type is recognized in other regulations dealing with copy size:

The Fair Packaging and Labeling Act sets a minimum height of 1/16 inch for the declaration of contents on small (less than 5 square inches) packages.

" (h) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be

. . . *continued*

uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less.

The cosmetic ingredient labeling regulations set a minimum height of 1/16 inch for ingredient listings, although provisions are made for accepting a smaller size on very small packages. One-sixteenth of an inch is equal to 4½ points.

The Nutrition Education and Labeling Act sets a minimum 4½ point type size for labeling of small packages.

" (6) All information within the nutrition label on packages that have a total surface area available to bear labeling of less than 12 square inches shall have type size no smaller than 4.5 point; packages that have from 12 to 40 square inches of surface area available to bear labeling shall have type size no smaller than 6 point; and packages with more than 40 square inches available to bear labeling shall have type size no smaller than 8 point, except that on packages with more than 40 square inches of available surface area, type size no smaller than 6 point may be used for the listing of information on *beta*-carotene, as specified in paragraph (b)(3)(iv) of this section, for the headings required by paragraphs (b)(3) and (b)(4) of this section (i.e., "Amount Per Serving" and "% Daily Value"), and for the footnote required by paragraph (b)(4)(v) of this section."

Most recently, the FDA on September 23, 1997 issued final regulations for nutrition labels for dietary supplements which sets a 4.5 point type size for labeling of small packages, and for larger packages where a large amount of dietary ingredient information is required:

" (I) All information within the nutrition label on small-sized packages, which have a total surface area available to labeling of less than 12 square inches, shall be in type size no smaller than 4.5 points;

" (ii) All information within the nutrition label on intermediate-sized packages, which have from 12 to 40 square inches of surface area available to bear labeling, shall be in type size no smaller than 6 point, except that type size no smaller than 4.5 point may be used on packages that have less than 20 square inches available for labeling and more than 8 dietary ingredients to be listed and on packages that have 20 to 40 square inches available for labeling and more than 16 dietary ingredients to be listed."

[62 Fed. Reg. at 49858 (September 23, 1997)].

In adopting the 4.5 point type size as a readable minimum, FDA cited as its principal source the Nonprescription Drug Manufacturers Association Label Readability Guidelines used for over-the-counter drugs [Id. at 49838 (September 23, 1997)].

While NDMA does not suggest that 4.5-point type be made the target print size for labels, we strongly believe that 6 points should not be set as a regulatory minimum. Instead, the size of print on the information panel of OTC drug products should be as large as practicable, within the limits of label size, package format, and the amount of information required.

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[1] Kahn, Harold A., et al., "The Framingham Eye Study. I. Outline and Major Prevalence Findings," *American Journal of Epidemiology*, 105, 1977, pp. 17-32.

[2] Smith, S.L., "Letter Size and Legibility," *Human Factors* 21 (6): 661-670 (1979)

WB/WS/b
10/3/97

EXHIBIT 8

Visual Acuity in Reading Nonprescription Drug Labels

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Co-Investigators:
Dr. John Bachynsky
Dr. Ben Doz

Introduction

The use of nonprescription medication is increasing as the sales of nonprescription drugs ($4.6 billion) in 1991 approach that of prescription drugs ($4.69 billion).[1] Increased drug use in the elderly is also at a high level, with 79 per cent of respondents in one study reporting taking one or more medications recently.[2] There have been continual improvements in the medication marketed and the medications now available to the public are more effective and potentially more toxic if misused. With this increased use and potential toxicity the public is at risk unless the medication is used appropriately. Some studies have shown that there is a lack of knowledge about the appropriate use of the medication and inappropriate use of some nonprescription medication.[3,4,5]

...there is a potential health problem in that a significant proportion of the public, particularly those with vision defects, cannot accurately read nonprescription labels...

Education of the patient to use the medication properly is the key element of reducing the risk of harm from nonprescription drugs. Currently, the main method of conveying information to patients on the proper use of nonprescription drugs is the provision of instructions on the label of the package. The underlying assumption is that the label information is clear, that the reader can understand it and that the print is readable to the patient. From the Canada Health Survey it was found that 42.2 per cent of the population reported no difficulty with seeing but needed corrective lenses. Another 4.6 per cent reported trouble seeing clearly.[6] Thus, nearly half of the population may have some degree of visual incapacity.

With an aging population the implications of declining visual acuity are a potential problem in the reading of nonprescription drug labels. It is known that in the elderly there is a requirement for more light for visual acuity and that the threshold for light seems to fall four per cent per year from the ages of 22 to 43 years.[7] In the elderly there are physical changes in the eye which results in the lens becoming more dense, cloudy and less elastic. The aged lens tends to scatter light more than a young lens and this reduces the amount of light reaching the retina, and alters the color sensitivity and glare that interferes with the visual image.[8]

The Decima study sponsored by the Health Protection Branch in 1990 found that 42 per cent of respondents reported that drug labels were difficult to read.[9] The factors influencing the readability of labels is one of interest and importance to health professionals.

Investigation of prescription labels showed that some elderly people would have trouble reading them.[10] Factors that make the label more difficult to read include: small type size, glossy surface from transparent tape, glossy labels, dot matrix print, and grey rather than black print. These were evident in the majority of prescription containers examined. It was recommended that pharmacists use

larger print size (14-pitch instead of 10), greater print density and minimized glare on the label surface.

The extent to which individuals have difficulty in reading nonprescription labels, particularly those with vision defects, is of significance if greater reliance is to be placed on self medication. This in turn is dependent on the patients being able to accurately read the instructions on the label. It was decided to conduct a study of the ability of the public to read labels. This would examine the influence of the size of type used, type font, background contrast for the type, and the background brightness or reflectance of the nonprescription drug label surface. Readability in this study refers to the ease, speed and accuracy in reading the information.[11] The visual acuity needed to read the instructions on the labels of nine commonly used nonprescription products was measured in the study.

The study of visual acuity was conducted on patients visiting an optometrist. This enables the measurement of visual acuity and the ability to link visual acuity with the ability to read nonprescription drug labels. A pharmacy student and an optometry student conducted the tests on the subjects.

Methodology

Nine commonly used nonprescription drugs were used to evaluate the readability of the instructions on the drug packages. The products selected were from the categories of analgesics, cough and cold remedies and gastrointestinal products. Three products were chosen from each category with differing print size, print type and background color. Attempts were also made to have differing surface reflectance and color contrast. The print size and font used on each package was determined by referral to a printing technician.

The variety of colors included in the sample was a deliberate decision to measure the influence of color on readability. Of particular interest was the use of blue on labels as it is reported to be the most difficult to read due to contrast. Contrast between the print and the background consisted of dark letters on a lighter background for six products, while Anacin, Nyquil and Diovol used white letters on a blue background.

Surface reflectance was measured under the lighting levels normally found in a pharmacy. This was determined by measuring the lighting level in the nonprescription drug section, at eye level in eight pharmacies. The eight pharmacies represented different types of community pharmacy (two independent pharmacies, three chain pharmacies and three grocery store pharmacies) in Edmonton.

Surface reflectance was measured at a light level of 850 lux, the average level found in the pharmacies. It was measured at angles of 30 and 60 degrees using the same lightmeter used for the lighting level measurements, a Paulux Electronic II lightmeter. Surface reflectance is the proportion of light th is reflected/absorbed by a surface. It wi vary with the angle of projection of th light, the color of the surface, the inten sity of the light and the nature of the sur face.[12]

Visual acuity is the ability of the eye to resolve patterns under ideal conditions of brightness and contrast. It determines our ability to read fine print and to recognize small objects at a distance. In this study the visual acuity was determined by an optometrist under the uniform conditions of an eye examination. Measurement of visual acuity is based on the Snellen method and is stated as a fraction whose numerator is 20 (the distance at which the test is made) and who denominator is the distance at which a letter can be seen.[13]

The sample of 49 patients was selected from patients attending an optometric clinic in Edmonton during July 1993. They were recruited by the optometric intern after having an eye examination and indicated that they were willing to spend the additional time. They were placed in a room with light levels similar to that found in the community pharmacies.

The visual acuity and color vision of the patients was tested by the optometric intern. Package labels of nonprescriptior drugs were then shown to the patients by the pharmacy intern. The patients were then asked to read out the instructions or the package for each of the nine products. The instructions for use on each of

Table 1:

Significance of Visual Ratings

Visual Rating Snellen	% Visual Efficient	% Visual Loss
20/20	100.0	0.0
20/30	91.4	8.6
20/40	83.6	16.4
20/50	76.3	23.7
20/60	69.9	30.1
20/70	63.8	36.2
20/80	58.5	41.5

Source: American Medical Association

Table 2:

Age Distribution of Subjects

Age	Number of Subjects	Per Cent
15-20	7	14.3
21-30	8	16.3
31-40	10	20.4
41-50	8	16.3
51-60	5	10.2
61-70	9	18.4
71-80	2	4.1

Table 3:

Relationship of Print Size and Visual Acuity

Product	Print Size	Visual Acuity Required
Aspirin	4-point	20/30
Fowlers Mixture	6-point	20/40
Anacin	6-point	20/40
Algicon	6-point	20/40
Nyquil	7-point	20/50
Ornade	7-point	20/60
222-AF	7-point	20/60
Diovol	8-point	20/60
Benylin DM-D	11-point	20/80

the nine packages were similar in length and level of difficulty.

The package labels were presented to the subjects in random order and the number of words misread or missed on each label was recorded. There was no limitation on the time taken to read the labels. Comments made by the patients in addition to their reading of the label instructions were also recorded. Patient age and education were also recorded.

Results

There were 49 subjects in the study, 32 female (65%) and 17 male (34%). The age range was 15 to 79 years. Six had an elementary school education, 26 a high school education, and 17 attended university. Their visual ratings were 20/20 or better.

The results of the analysis of the packages of the nonprescription products is presented in Table 3. The print size varies from 4-point (smallest) to 11-point (largest). Prescription labels are normally 10-12-point with a recommendation for elderly patients that they be 14-point.

Helvetica font in several forms was used in all but one label; the other font used was Optima. Upper and lower case letters were used on seven of the eight labels and only one, Nyquil, used upper case only.

There was a large variance in the surface reflectance of the product packages ranging from 20.5 lux to 30 lux at 30 degrees and 3.5 to 6 lux at a 60 degree angle. Algicon with a high surface reflectance of 5 lux has a white surface while Anacin with a blue background has a lower reflectance of 3.5 lux.

Visual acuity is influenced primarily by the print size but also by the color contrast and the spacing of the letters. Under standard conditions the visual acuity to read the print size was determined for each of the products and the relationship is presented in Table 3. The influence of color contrast is shown by a comparison of Nyquil and Ornade, both of which have 7-point type. Nyquil required visual acuity of 20/50 to be read while Ornade required only 20/60. Similarly, the dark blue background of

Table 4:

Ability to Read Labels Without Error

Per Cent of "Instructions for Use" that could be read

Product	100%	98-99%	85-97%	1-84%	0%
Aspirin	57.2	20.4	14.2	-	8.2
Fowlers	65.3	16.3	12.2	6.1	-
Anacin	65.3	16.3	12.2	6.1	-
Algicon	81.6	10.2	6.1	2.0	-
Nyquil	63.3	16.3	14.2	6.1	-
Ornade-DM	61.2	18.4	12.2	8.2	-
Diovol	73.5	16.3	6.1	-	-
222-AF	67.3	16.3	12.2	4.0	-
Benylin DM-D	83.7	16.3	-	-	-

Table 5:

Relationship between Visual Acuity and Ability to Read

Number of labels that could be read by patients

Visual Acuity	9	8	7	6	5	4	3	2	1	0	Total
20/20 (= +)	9	12	1	5	2	5	1	1	0	0	36
20/30	0	0	2	2	2	2	0	1	0	0	9
20/40	0	0	0	0	0	2	0	0	0	0	2
20/50	0	0	0	0	0	0	0	0	1	1	2

Diovol made it more difficult to read, requiring 20/60 acuity even though the print size was larger.

The ability of the subjects to read the instructions on the labels of the nine products is presented in Table 4. This table is based on the number of errors or inability to read the text of the instructions for use.

The size of type can be seen to be the most important factor in the ability of the subjects to accurately read the instructions. Contrast also plays a role. Although both Anacin and Algicon have 6-point type size , Anacin had white letters on a black background while Algicon had black letters on a white background which gives a better contrast. This change resulted in Algicon having more legible instructions that could be read with fewer errors, with 91.8 per cent of the subjects able to read over 97 per cent of the label while only 81.6 per cent of the subjects could read Anacin label at the same level of uracy.

Only nine subjects (18%) could read accurately the instructions on all nine labels at the 98 per cent accuracy level (Table 5). This reveals that even some people with normal vision had difficulty reading the labels. For those with refractive errors the scores were lower. For those with a visual acuity of 20/50 only one label at most could be read accurately. Based on the refraction tests and the print size, subjects with visual acuity of 20/30 or better should be able to read all the labels. This was not the case.

Conclusion

This study reveals that there is a potential health problem in that a significant proportion of the public, particularly those with vision defects, cannot accurately read non- scription labels. Since the primary source of information on how to use the medication is the label, this finding would indicate that people uld have to develop a method of com- sating for their inability to read the instructions. It is evident, however, that there is a significant exposure to risk that needs to be examined.

The need for someone to be available to provide information on the method of using the medication provides pharmacists with an opportunity to improve care and reduce the risk from drug related problems.

Colors that allow high contrast for easy reading should be used and green and blue should be avoided. These colors continue to be used and reduce the ability of the patients to accurately read the label. Finally, highly glossy surfaces should not be used, yet they were used in all cases. A number of factors contribute to the readability of nonprescription drug labels.

Discussion

The importance of lighting levels is raised in this study. There are widely varying lighting levels in pharmacies and it is desirable to have the light intensity high enough to make the print visible but not to cause any glare. Glare is a particular problem for the elderly. For these reasons lighting in community pharmacies should be designed to facilitate the reading of product labels.

Pharmacist services to those who have difficulty reading labels should consist of providing written instructions in larger print, counselling patients on the use of the products and keeping a record of the patient's visual acuity so that any printed material would be legible.

Readability of labels is an issue that the nonprescription drug industry is now addressing. The Nonprescription Drug Manufacturers Association in the United States has published Label Readability Guidelines.[14] They set out suggested procedures based on the use of designated individuals or groups. Many of the guidelines reflect the findings in this study. Of particular interest is the guideline that the print size be at least 4.5 points if black on white or similar high contrast dark on light print is used, i.e. under the best conditions.

It is now accepted that the use of color, size and type of font and surface reflectance needs to be reviewed with consideration of the target population. Better use of space on the label to improve readability would require reducing the space available for pictures, logo, etc. This type of tradeoff is part of label design.

Plain, upright letters with no ornamentation should be used and the Helvetica font is recommended by the Canadian National Institute for the Blind. It was the font used on most of the labels. It is also recommended by the CNIB that both upper and lower case be used rather than all capitals, and this also was found in the study.

Pharmacists should be aware that a large proportion of the public cannot accurately read the labels on nonprescription drugs. This fact needs to be added to the lack of comprehension of the instructions and difficulties in the understanding of English and French.

References

1. Health Information Division, Health Canada, April 1994. Personal communication.
2. Segall, A., "A Community Survey of Self-Medication Activities", Medical Care (1990)28:301-310.
3. Rantucci, M.J. and Segal, H.J., "Over-the-Counter Medication: Outcome and Effectiveness of Patient Counselling", J. Soc. Admin. Pharm.(1986)3:81-91.
4. Lyons, H.P. and Partridge, M.B.R.,"The Supply of Unrecommended Laxatives from Community Pharmacy", Pharm. J.(Supplement), 1993, R29.
5. Salerno, E., Ries, D.N., Sank, J., West, E. and Currier, M., "Self-Medicating Behaviours", Fla. J. Hosp. Pharm.(1985)5:13-28.
6. The Health of Canadians, Report of the Canada Health Survey, Minister of Supply and Services, Ottawa, 1981, p.124.
7. Boorish, Clinical Refraction 19—, publisher, p.358.
8. Marmor, M.F., "Visual Changes with Age", chapter 3, pp.28-35, in Caird. F.I. and Willimason, J., The Eye and its Disorders in the Elderly, 1986, Wright, Bristol.
9. Decima Research, Attitudes, Perceptions and Behaviour Relating to Ethical Medicines, Supply and Services Canada, Ottawa, 1990.
10. Jinks, M.J., et al., "Prescription Labels for Aging Eyes", Am. Pharm.(1989)NS29:32-33.
11. Marmor, M.F., "Visual Changes with Age", chapter 3, pp.28-35, in Caird. F.I. and Williamson, J., The Eye and its Disorders in the Elderly, 1986, Wright, Bristol.
12. Lampi, E., "The Sources of Light and Lighting at Work", Acta. Opthal. Suppl. (1984)161:66-83.
13. Abrams, D., Chapter 20, Visual Acuity, in Duke-Elder's Practice of Refraction, 1993, Churchill Livingstone, Edinburgh, pp.145-153.
14. Label Readability Guide, Nonprescription Drug Manufacturers Association, Washington D.C., 1992.

EXHIBIT 9

Founded 1881
NDMA
NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

Better Health
Through Responsible
Self-Medication

New OTC Labels:
Industry's Proposal for Even Easier to Use OTC Labels

Comments by the Nonprescription Drug Manufacturers Association
at the FDA Public Hearing on OTC Labeling
September 29, 1995

Good morning. Mr. Chairman, Members of the Committee, Ladies and Gentlemen. I am Dr. Bill Soller, Senior Vice President and Director of Science & Technology for the Nonprescription Drug Manufacturers Association. NDMA represents over 75 manufacturers and distributors of nonprescription medicines and by sales over 95% of the OTC marketplace. With me today is Mr. Bill Bradley, NDMA Director of Technical Affairs.

NDMA welcomes the opportunity to again address FDA on the subject of OTC label readability. We have extensive experience in this area and share with FDA the goal of even easier to use OTC labels.

Today, we ask FDA to amend a single existing regulation to create standardization (order, headings, subheadings), while maintaining flexibility (other label text, format, design). This will allow companies to simplify OTC label language and achieve the goal of easier to use OTC labels through design, format and word changes without over-regulation that would cause needless delay and wasteful use of valuable resources.

Our comments are in four parts:

(see next page for Index)

... continued

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Index

I. Overview of Label Readability

In 1990, the State of California[1] first brought the issue of label format and design into focus nationally, and in 1991 NDMA members adopted label readability guidelines[2] that identified all of the factors that affect label readability, including:

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1 California Assembly Bill 2713, 1990.

2 Appendix A: NDMA's Label Readability Guidelines, 1991..

... continued

1. Technical factors, or those that relate to how the label is constructed and over which industry has control;

2. Regulatory factors, factors over which FDA has sole control -- such as the specific label text that they require us to have verbatim on our labels;

3. Physiologic, pathophysiologic and socioeconomic factors, over which FDA and industry have little control (such as underlying ophthalmic disease, a person's choice to wear corrective lenses or use adequate lighting etc.).

Since the start of our efforts in this area, industry has changed literally thousands of miles of OTC labels per our guidelines, and we have received commendations from those in California with whom we worked as well, as from FDA, which has recommended broad application of our guidelines. All this we have called "Phase I Label Readability."

In 1991 we stated in our guidelines[2] that before we would be able to simplify the language on our OTC labels to help comprehension, we would need FDA action to allow us to undertake Phase II Label Readability, which has as its goal, making OTC labels even easier to use through label design, format and word changes.

Our proposal today is a plan of action for the agency that will enable government and industry to accomplish the goal of Phase II Label Readability swiftly, efficiently and effectively.

II. How to Best Manage the Next Step:

Given the work that has been done by industry, how do we manage the next step? Can we build on our successes and a willingness by industry to work with FDA? To answer these questions, lets look at some facts describing the current situation.

1. FDA Mandates What Goes on the OTC Label, Not Companies.

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The OTC Review[3], started in 1972, has resulted in OTC monographs for every OTC marketed GRAS/E ingredient. With the exception of Indications, most language now on OTC labels of monograph'd ingredients must appear verbatim per the applicable monograph. Indications may appear in alternate, truthful and not misleading language under the Flexibility Policy[4] for OTC labeling. NDA's OTCs must also bear verbatim language as specified for each product.

2. OTC labels have all of the information needed for safe and effective use of these products by consumers in a self-care setting. There is no information gap.

We are post-OTC Review, not pre-NLEA. For all practical purposes, all of the information that is needed on the OTC label for safe and effective use of the medicine by the consumer is there now -- and, in fact, has been there for many years[5]. In contrast, the Nutrition Education and Labeling Act of 1993 was enacted to fill an information gap for food labels. No such information gap exists at this time for OTC labels, as attested by their excellent safety record.

3. Consumers Report Reading OTC Labels and Using OTCs Responsibly.

Nine nationally representative studies over the past ten years demonstrate that the vast majority of consumers report reading OTC labels before using them the first time and responsibly self-medicate --e.g., use OTCs only a third of the time that

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3 Federal Register 37(2): Over-the-counter drugs: Proposal establishing rule making procedures for classification, 85-89, January 5, 1972.

4 Federal Register 51(84): Labeling of drug products for over-the-counter human use, 16258-16267, May 1, 1986; Appendix D.

5 Code of Federal Regulations 330.10 (a)(4): Standards for safety, effectiveness and labeling. "(iv) Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use."

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they might and for much less than the limit of use specified on the label[6].

Of parenthetical note, a recent survey by the Wirthlin Group asked consumers about their "off-the-street" unaided knowledge of OTC medicine labels -- i.e., without showing the subjects a typical OTC label, or without testing an OTC label in a "use" situation. It is neither surprising nor alarming that unaided awareness of the components on an OTC label is relatively low (i.e., not in the typical percentile range seen in recent switch-related label comprehension studies), since this is irrelevant to actual OTC use situations where consumers have the label in front of them. Little weight should be given to the Wirthlin report (April 1995 *National Quorum Report* for The Council on Family Health).

4. **No Public Health Problem**.

Given the previous observations, it is not surprising that there has not been a demonstrable public health problem associated with OTC labels currently constructed through applicable FDA regulations and the industry's voluntary label readability program.

For example, a recent comprehensive review of the medical literature relating to OTC drug interactions by the Degge Group[7] concluded:

> "In summary, the potential for drug interactions involving OTC medications is real, but the actual occurrence of OTC drug-drug interactions has been rare in published studies of drug-related hospital admissions. We conclude that OTC drug interactions are not a significant public health problem."

5. **No Clear-cut Difference Between Current OTC labels and New Format**

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6 Appendix B: Key findings from of Nine Nationally Representative Studies on Consumer Relating to Consumer Use and Knowledge of OTC Medicines

7 The Degge Group: OTC Medications and Drug Interactions. NDMA Files, 1995

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Labels in Label Comprehension Studies of Switch Candidates.

Recent label comprehension studies[8] on Rx-to-OTC switch candidates (e.g., H2 antagonists) have demonstrated an equally high rate of information transfer (i.e., no measurable gain) for OTC labels constructed per the industry guidelines and those with a new format. In one recent instance (hair restorer candidate), the "statistically significant" differences reported between the test and current labels do not apply generally to current monograph OTC labels, since none of the studied labels were constructed similar to current OTC labels, the same text language was not used for the comparison labels and/or the language tested was not of the type now used on any current OTC monograph label.

6. FDA Asks Many Questions, Yet the Goal Is Simple: Even Easier to Use OTC Labels.

FDA lists many questions in the Federal Register announcement of August 16, 1995[9] on OTC labels, but many -- if not most -- do not specifically need to be answered through the time- and resource-intensive accumulation of data in order to undertake a reasonable step to making OTC labels even more consumer friendly. Industry's proposal defines a workable approach focused on a definable goal of easier to use OTC labels.

7. A Second OTC Review?

FDA proposes to use its own experts to develop revised language for OTC labels with opportunity for consumer testing of revised language. We hope that this does not mean that FDA is contemplating a word-by-word, monograph-by-monograph review to make OTC labels even easier to use. Given that there are over 600 active ingredients in 80 monographs covered by the OTC Review, which began

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8 Personal communication from NDMA member companies and presentations at the relevant meetings of the Nonprescription Drug Advisory Committee/

9 Federal Register 60 158): Over-the-counter drug labeling: Public hearing, 42578-42581, August 16, 1995.

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twenty years ago and has yet to be completed, it is doubtful that FDA's proposal could be handled by one Federal Register publication. If, in fact, the process were to be monograph-by-monograph, one would then expect a time- and resource intensive process -- in effect, a second OTC Review. On the other hand, industry's proposal provides an approach that is both time- and resource-conservative. It can be completed swiftly, effectively and efficiently.

8. **The Current Flexibility Policy for OTC Labeling Has a Good Track Record of Industry Compliance and a Sound Enforcement Policy and Is a Success that Can Be Built Upon.**

In 1986, FDA adopted the Flexibility Policy (footnote 4 and Appendix D) that permits alternate, truthful and not misleading language to product claims relating to Indications of Use and Directions (e.g., see pages 16528 and 16263 of Appendix D) . All other OTC label language must appear verbatim as found in applicable OTC monograph regulations; there is little room allowed by FDA for text consolidation and simplification, particularly for warnings. Industry has had an excellent record of complying with the Flexibility Policy, and FDA has a sound enforcement policy to find labels that might be considered misbranded because the alternate terms are not truthful or are misleading. The Flexibility Policy has thus been a success and can be built upon to create even easier to use OTC labels. Indeed, it is in the best interests of companies, from the standpoints of good business practice and legal requirements, to ensure that any alternate language that is used is substantively equivalent to that in the applicable OTC monograph. This would be especially true for Warnings, which would be covered under such a flexibility policy under industry's proposal.

9. **Industry is Willing, Already Committed to Easier to Use OTC Labels, and Wanting to Do Even More.**

Industry's commitment to easier to use OTC labels is in the interest of both the consumer and companies. We knew in 1991 when we adopted our label readability guidelines -- as we know now -- that even more can be done. Our

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proposal to initiate FDA action now so that companies can simplify their OTC labels through design, format and word changes is definite support for industry's willingness to move forward.

10. Industry's Proposal Is Consistent with President Clinton's Call for Regulatory Reform

On March 4, 1995, President Clinton[10] called on all corners of government to consider steps to reform the government regulatory process, including seeking to curb obsolete regulations; rewarding results, not red tape; creating grass roots partnerships; and negotiating, not dictating. President Clinton said:

> "It is time to move from a process where lawyers and bureaucrats write volumes of regulations to one where people work in partnership to issue sensible regulations that impose the least burden without sacrificing rational and necessary protections." (see footnote 9; Appendix E)

In summary, the current situation is unique indeed -- and offers a unique opportunity. We have: an industry taking action and willing to take more; an Executive Branch defining partnership as the modus operandi; no clear cut major health or safety benefit from proposed alternative labels; and a marketplace where there is no demonstrable public health problem. Yet, we all agree that even more can be done -- and should be. But how -- so that it is "win-win-win" for consumers, FDA and industry? We think our proposal meets this unique opportunity with a workable solution.

III. Industry's Proposal for New OTC Labels

A. Detailed Proposal

NDMA proposes that FDA should also establish:

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10 The White House, Office of the Press Secretary: Memorandum for heads of departments and agencies from President William Clinton, March 4, 1995.

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1. A standard order of information of the following primary information: Active Ingredient(s) & Action(s); Uses, Directions and Warnings;

2. Standard highlighted headings for major text sections: Active Ingredient(s); Action(s); Use(s) or the word "For" followed appropriate by the appropriate phrase, e.g.,"the temporary relief of ..." or its substantive equivalent; Directions and Warnings. Note the phrase "Drug Interaction Warning" or -- as FDA has proposed -- "Do not mix drugs" would no longer be used.

   Highlighting would be accomplished in a variety of ways at the option of the manufacturer, including boldface, all caps, color letters, color background, underlining, boxed words, etc.

3. Adopt a standard set and order of highlighted subheadings for the Warnings Section and explicitly state that companies may list warning text in bulleted lists or in paragraph form, as follows:

- "**Do not use before consulting a doctor if you have:**..."
  [list contraindicated conditions];
- "**Do not use before consulting a doctor if you are:**..."
  [consolidate the pregnancy nursing warning and drug interaction precautions];
  The signal phrase, "Drug Interaction Precaution" would no longer be used, saving text, without compromising a special placement of such warnings under a special "plain English" subheading.
- "**When using this product:**..."
  [insert limit of use warning, warnings to consult a doctor if a symptom persists, side effect information, etc., per the relevant monograph].

   a. Highlighting of the warnings subheadings would be accomplished as described above for standardized headings.

   b. Text under these subheadings in Warnings would be substantively

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equivalent to OTC Monograph language, via an amended Flexibility Rule..

c. Freedom for companies to use alternate, truthful and not misleading Monograph-derived language can be accomplished with limited changes to Monograph warnings, but with substantial consolidation of language and word savings for warnings, for example, of 30-50% (see below).

d. In a limited number of instances, the second subheading ("Do not use before consulting a doctor if you are:...") would be, "**Do not use if:...**", under circumstances where the instruction is to not use the product irrespective of a doctor's consultation (e.g., MAO inhibitor warning). In such cases, the pregnancy/nursing warning would read, "• pregnant or nursing a baby, without first consulting a doctor", while the MAO inhibitor warning would be bulleted (after the pregnancy/nursing warning) per other drug/drug interaction warnings.

B. Text Prototypes for Warning Subheadings:

Some examples are shown below to demonstrate how easy it would be under industry's proposal to make our labels easier to use, if FDA would allow us to do so by adopting the proposal into regulation. We have undertaken this exercise in most OTC categories and have found our approach generally applicable across OTC categories.

In the case below, while the word savings is about 18%, and the text is obviously simplified by being broken up into shorter information "takes."

Bulleting also improves the consumer friendliness of the label warning -- whether done in lists or in paragraphs (as here) because of space limitations.

See table, next page.

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OTC Nasal Decongestant

New OTC Label Format Number of Words 27	Single Paragraph Format 33
Do not use before consulting a doctor if you have: • heart disease • high blood pressure • thyroid disease • diabetes • difficulty urinating due to enlargement of the prostate gland	Do not take this preparation if you have heart disease, high blood pressure, thyroid disease, diabetes, thyroid disease, or difficulty urinating due to enlargement of the prostate gland unless directed by a doctor.

In the case below, consolidating the pregnancy/nursing warning and drug interaction warnings under one special subheading yields a very substantial word savings of about 50%. Bulleting also improves consumer friendliness.

OTC Antihistamine

New OTC Label Format Words 29	Single Paragraph Format 54
Do not use before consulting a doctor if you are: ➤ Pregnant or nursing a baby; ➤ Presently taking a prescription drug for high blood pressure or depression, sedatives, or tranquilizers	As with any drug, if you are pregnant or nursing a baby, seek the advice of a health care professional before using this product. DRUG INTERACTION PRECAUTION: Do not take this product if you are presently taking a prescription drug for high blood pressure or depression, sedatives, or tranquilizers, without first consulting your physician.

Finally, in the subheading concerning precautions during use, word savings is also realized, and especially text separation of lengthy text through bulleting.

See table, next page.

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OTC Topical Analgesic

New OTC Label Format Words 73	Single Paragraph Format 86
When using this product: • Avoid contact with eyes and mucus membranes. • Do not use with heating pads or heating devices, other ointments, creams, sprays, or liniments. • Do not apply to wounds or damaged skin or bandage tightly. • Stop use and consult a doctor if: ✦ condition worsens; ✦ symptoms persist for more than 1 week or clear up and occur again within a few days; ✦ skin irritation develops. KEEP OUT OF THE REACH OF CHILDREN.	Avoid contact with eyes and mucus membranes. DO not use with other ointments, creams, sprays, or liniments. DO NOT USE WITH HEATING PADS OR HEATING DEVICES. If condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days, discontinue use of this product and consult your doctor. Do not apply to wounds or damage skin. Do not bandage tightly. If skin irritation develops, discontinue use and consult your doctor. KEEP OUT OF THE REACH OF CHILDREN.

C. Label Prototypes:

Label prototypes[11] without detailed text and showing the basic framework of standardization proposed by industry (i.e., order of primary information, standard headings, and warning subheadings) are shown in Appendix C.

Because packages come in different configurations, the basic label format should be able to be adaptable, and examples are shown in Appendix C. These examples are meant for discussion purpose only and do not represent other variations in the basic format proposed by industry, which can be done while still achieving the goal of easier to use labels.

Examples of industry's proposal in full text prototypes for a typical single ingredient are also shown in Appendix C. The label of OTC diphenhydramine -- an antihistamine -- is shown in three different applications of industry's proposal: two carton labels for blister packs and a wrap label for bottles. An Antacid label is also shown. Significant word savings with increased white space is evident in all examples.

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11 Appendix C: Label Prototypes: For discussion purposes.

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The American consumer is sophisticated enough to handle these package-specific variations and will be aided in doing this through the standardization of order, headings and subheadings.

D. Advantages of Industry's Proposal:

Some of the advantages of industry's proposal for a dual approach of standardization with flexibility to create even easier to use OTC labels include:

- With standard headings, consumers can reproducibly find major text sections in a reproducible order.

- The standardized order of warning subheadings provides a rational flow of medical information, with contraindications to initial use of the product followed by warnings during use.

- The warning subheadings allow virtually all OTC warnings to be consolidated and simplified with word savings for warnings, for example, of 30-50%, thereby increasing white space and allowing the use of increased type size.

- Warnings subheadings allow the complicated text to be broken up into smaller information segments and the use of bulleted lists, which also appear more consumer friendly.

For smaller packages or larger packages with greater amounts of text material, the bulleted phrases can be placed in paragraph form (with the bullets) under the particular warning subheading, thereby allowing efficient use of scarce label space, while maintaining highlighted breaks in text.

As stated, FDA's amendment of the Flexibility Rule (Appendix D) is needed to accomplish this very workable approach to easier to use OTC labels. The Flexibility Rule was adopted [illegible]986 and provided [illegible]ndustry could use alternate, truthful and not misle[illegible]erms for Indications, although other labeling language in the OTC

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monographs would need to be placed verbatim on the label.

At the time, FDA explicitly recognized in the Federal Register that even in the absence of a Flexibility Policy, there was no evidence of widespread abuse and that FDA had a sound enforcement policy to ensure adequate enforcement.

> "Experience does not demonstrate any significant widespread patterns of abuse, even in the absence of established exclusivity provisions and there is no reason to expect such abuses to emerge under the revised policy." (Federal Register 51:16259, 1986; footnote 4).
>
> "FDA intends to carefully examine the labeling of OTC drug products to ensure that any alternative language that manufacturers use does not go beyond the approved indications for use, thereby causing the drug to become a 'new drug' or 'misbranded' or both under the act. If unacceptable language is discovered, the agency will take appropriate regulatory action. The agency believes that a sound enforcement program will minimize any unfair competition that would otherwise result from improper labeling." (Federal Register 51: 16260, 1986; footnote 4).

Since the implementation of the Flexibility Rule in 1986, industry has had a great track record, and FDA has a sound enforcement program. Simply put, it is clearly in the companies' best business interests from the standpoints of legal concerns and good business relations to be as close to the Monograph language as possible in terms of uses, directions and warnings.

The chief advantage to amending the Flexibility Rule is that the appearance of even easier to use OTC labels on the marketplace can occur at a faster and more resource-conservative way than could occur through a monograph-by-monograph approach with public review and comment rule making. A second OTC Review is simply not needed. In addition, FDA enforcement activity is not compromised. FDA still maintains the ability to make a determination that a label does not meet the intention of a regulation -- as it always has been able to [illegible]inally, as stated, th[illegible]posed approach is consistent with President Clinton's directive regarding avoiding over-regulation.

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E. Comments on Additional Points Raised by FDA:

Several additional points raised by FDA in its August 16th announcement of the September 29th meeting are touched on here and will be amplified in NDMA's follow-up comments.

First, we have made our position very clearly known to FDA on the Principal Display Panel (PDP). We think the current discussion on label design and format should pertain only to the Information Panels, not on the PDP -- which is the industry's main form of communication with the consumer with respect to product awareness.

The PDP is a valuable tool with which industry communicates with consumers. Nowhere else on the product label is there comparable opportunity for a manufacturer to distinguish his products from those of its competitors. This ability to distinguish one product from another is vital to effective communication with buyers and to successful competition in the marketplace. For the consumer, it fosters freedom of choice.

In the absence of any evidence of significant harm or widespread public confusion under labeling regulations already in place, drastic new changes in the PDP regulations would be without consumer benefit and costly to industry.

Second, the issue of smaller packages. Downsizing is an issue, even for packaging. In fact, larger packages with greater amounts of label language (e.g., a four way cough/cold product) can also be affected by space limitations.

Here are the pressure points:

- ✦ Consumers want convenience sizes, and a lot of information is required on the OTC label.
- ✦ There is a statutory need to meet slack fill requirements[12], such that there is a limit

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12 California Slack Fill Enforcement guidelines for Cosmetics, Toiletries, and Fragrances and Nonprescription or OTC Medicines, 1989.

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as to how large we can make our package without seeming to be deceiving from a net contents standpoint.

- ✦ Environmental concerns, such that companies are moving to carton-less packages.
- ✦ Smaller sizes are a definite convenience for consumers.

The message is that package size variations need to be thought about up-front. For example, we have tried to minimize FDA's prototypes to smaller package sizes, but find FDA's prototypes cannot be reduced to actual size packages. Therefore, we considered this in developing our approach, and we are able to maintain standard order, standard subheadings and bulleting in paragraph format and still reduce our prototypes to convenience sizes. An example of an antacid roll is available for you to consider in this regard.

Pictograms are attempts to describe a statement, while icons and symbols are merely alerting devices. On pictograms -- a picture is worth a thousand words and that is the problem with pictograms. Recent work by Hansen and Hartzema[13] indicates considerable confusion among the elderly and low-literate, with USP-DI pictograms (Appendix F). For example, common misinterpretations of pictograms included: (a) "take two pills by mouth an hour" instead of the intended meaning of "take two hours after meals;" (b) "take half your medication, then take the other half" instead of "take until finished." And, there's the issue of smaller labels. Thus, we support optional, not mandatory use of pictograms, icons, and symbols.

On type size, we recommend that FDA adopt the type size criteria of NDMA's label readability guidelines. Six point type is the desired minimum recommended by NDMA's label readability guidelines; 4.5 point type -- for smaller packages -- is the absolute

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13 Hansen, E. C., and A. Hartzema. Evaluating pictograms as an aid for counseling elderly and low-literate patients. J. Pharm. Marketing and Management 9(3): 41-54, 1995. "Results indicated that the pictograms were not very well understood by respondents: 54% were incorrectly identified at T1 [test period one, prior to the pictogram being explained to the respondents]. Respondents misinterpreted significantly fewer (32%) pictograms at T2 [test period two] after being told the meaning. Seven of the pictograms were misinterpreted by one third or more of the respondents at T2.

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minimum. A recent NDMA survey of 2000 labels showed that over 95% of the labels studied had a minimum type size of 6 points or greater.

By definition[14], a person with 20/44 visual acuity can read letters in 4.5 point type at 13 inches. Since words are 20% easier to read than letters, this translates to a person with 20/55 being able to read 4.5 point type at 13 inches. From the Framingham Eye Study[15], 98.5% of the general population has a visual acuity of 20/50 or better, with 95% of the 75-84 age group having 20/50 (best eye corrected; 99.5% of the 56-65 age group), and can, therefore, read 4.5 point type. Further, the National Center for Health Statistics[16] uses 20/50 as the cut off for determining serious visual impairment, such that those with less than 20/50 visual acuity should have help reading. Moreover, Smith[17] demonstrated that the 98% of the test subjects could read the equivalent of 4.5 point print at a distance of 13 inches. Finally, NLEA specifies 4.5 point type as a minimum size and even the Washington Post uses 4.5 point type for classified ads that measures the equivalent of 4.5 - 5 point type, where space is a premium. Thus, as an absolute minimum, 4.5 print type is reasonable for OTC labels, though not often used. Six point type is commonly used and preferred.

NDMA reported quarterly for three years on label readability to the government, consumers, and health professionals in California. The California Association of Ophthalmology, a group of medical doctors specializing in vision, has endorsed NDMA's guidelines on label readability and commended NDMA on the progress made.

In sum, no one factor determines label readability. Type size is just one factor. The available evidence supports a 6 point type size as a general rule for OTC labels, with the recognition that label size and extensive label text even on larger packages may affect the

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14 Davidson, D.W.: Visual Acuity. In: J. Eskridge et al. Procedures in Optometry. J.B. Lippincott, 1991.

15 Kahn, H. et al.: The Framingham Eye Study. Am. J. Epidemiology 106:17-32, 1977.

16 National Center for Health Statistics: Eye Conditions and Related Need for Medical Care Among Persons 1- 74 Years of Age. United States 1971-2. Series 1[illegible] No. 228, 1983.

17 Smith, S.L.: Letter Size and Legibility. Human Factors 21(6): 661-670, 1979

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determination of final type size. With the changes proposed by industry for label design, format and word changes, there should be word savings and thus the potential for use of larger type sizes.

With respect to testing, there are two basic issues: the question what, if anything, needs to be tested on the labels for monograph'd OTCs; the question of performance standards. Regarding the question of testing label elements, enough testing has been done to date in order for us to move forward with something important and meaningful for the consumer. For example, Hansen and Hartzema have shown the confusing nature of pictograms (see Appendix F); icons look "neat" at first blush, but recent studies (e.g., cholesterol lowering agent) indicate they provide no clear cut advantage; bullets make sense, but the H2 blocker and the hair restorer studies show no clear cut benefits in information transfer for current OTC monograph labeling. A standard order of standard headings is just good common sense, and so is a standard order for the standard warning subheadings, which allow not only text simplification but a logical organization to warning statements. We can move forward now with industry's proposal.

On the question of performance standards:

- There is no accepted validated method to assess minimum standards for technical factors affecting label readability;

- There is no agreed upon threshold criterion. No one technical factor can create label readability. Rather, it is logically all of the technical factors (e.g., color, contrast, brightness, substrate, among others) working in concert which determine a successful label. As such, many of these factors are interdependent, so that the execution of one of these factors will affect the expression of others.

- The experience to date from the switch-related label comprehension studies suggests that it is best to focus on discrete communication objectives particular to the switch candidate. Which label element would be picked for a general standard

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applicable to all 80 OTC categories? Would that be possible? If so, over how long a period of time?

- ✦ Would every label have to meet such performance standards? Would every label have to be tested? If so, would not this be even more than another OTC Review? Rather, an NDA-like product-by-product review? Is this really needed?

In sum, performance standards are certainly unworkable in the short term ... and also in the long term.

IV. Conclusion:

In conclusion, we hope we have a mutual goal with FDA of easier to use OTC labels through format design and word changes. We think the strategy should be -- and can be -- cooperative interaction.

And, we think the approach should provide for some standardization and allow for some flexibility. It can be built on a proven track record of the industry's involvement in label improvements and FDA's sound enforcement policy. And, it would be consistent with the Administration's policy on working with the regulated industry.

Thank you, I would be pleased to answer any questions.

WS/jq:OTCSUM.WPD:9/22/95:s9/26/95/9/27/95

EXHIBIT 10

National Consumers League
Founded 1899

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Linda F. Golodner, Executive Director

Dockets Management Branch,
(HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 4-62
Rockville, MD 20857

Docket No. 90-P-0201

Comments of

The National Consumers League

on

Print Size and Style of Print for Over-The-Counter Drug Products

August 5, 1991

Submitted by:
Mary E. Ponder
Deputy Director

90P-0201 D C57

The National Consumers League (NCL), a national, nonprofit membership organization representing consumers, recommends that the Food and Drug Administration (FDA) establish federal regulations on print size and style of OTC drug labeling. Further, the League urges the FDA to develop mandatory regulations requiring a minimum print size and particular styles of print as well as preferred contrast and color combinations for all OTC drug labeling. The League recommends that FDA develop these regulations for all three parts of the labeling; namely the label on the bottle, the package insert and the carton.

The League does not find that the voluntary guidelines of the Nonprescription Drug Manufacturing Association (NDMA) adequately address these concerns and urges the FDA to take an active role in promulgating and enforcing new regulations to assure readability of OTC product labeling. The results of the NCL Investigative Survey on Consumers' Ability to Read OTC Labels With Different Type Sizes (Question 7) suggest that regulations on type size and style should not be developed without more research and consumer testing, including comparing the public's ability to read labeling using different type sizes, style, contrast, color, as well as length of lines, etc.

Background

Currently, there are no statutory or regulatory requirements that specifically address the print size and style of the labeling of OTC drug products. Section 502 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 352] only states "the wording must be prominently placed." Implementing regulations vaguely refer to making the information noticeable. The most specific recommendations are for warnings to appear in boldface type on some OTC labels.

Yet, the Food, Drug, and Cosmetic Act clearly states that nonprescription (OTC) products, are safe when (emphasis added) consumers follow the directions and warnings on the label. The FDA has very detailed regulations specifying what manufacturers are requireds to print on a label: product name and statement of identity; ingredients; name and location of the manufacturer; net quantity of contents; indications for use; directions and dosage instructions; warnings; and expiration date. Drug manufacturers, without standardized federal regulations, have had varying success developing labeling that contained all the required information on a relatively small surface area. As a result, consumers frequently are unable to read the information that the FDA requires on the label.

The following are comments in response to the questions that FDA is seeking to address before making a final decision on the feasibility of establishing a federal regulation pertaining to

print size and style of OTC drug labeling.

1. Are current print sizes, types, colors, contrasts, backgrounds, etc., of OTC drug labeling adequate in providing readable information for individuals with normal eyesight and for those with poor or deteriorating eyesight?

The League does not find the present OTC drug labeling adequate for individuals with normal eyesight or for those with poor or deteriorating eyesight. Although the League is not aware of a large, documented study of the American public's ability to read a representative sampling of OTC labels, a significant Canadian study documents the problem. A 1990 study commissioned by the Drugs Directorate, Health Protection Branch of the Department of National Health and Welfare, "Attitudes, Perceptions and Behavior Relating to Ethical Medicines," [1] reported that 31 percent of the respondents found labels on nonprescription drugs **difficult** to read and another 11 percent found the labels **very difficult** to read. The survey used a proportionately representative random sample of 1000 Canadian residents, 18 years of age and older with a questionnaire containing seventy-one items.

In the United States, the 1990 passage in California of Assembly Bill (AB) 2713 requiring manufacturers of nonprescription drugs which are sold in California to evaluate and modify the

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[1] Decima Research, sponsored by the Drugs Directorate, Health Protection Branch, Department of National Health and Welfare, "Attitudes, Perceptions and Behavior Relating to Ethical Medicines," Research Report to the Department of National Health and Welfare, ISBN 0-662-57888-0.

labeling of their products to maximize the readability and clarity of label information, in both the cognitive and visual sense, is a reflection of growing consumer dissatisfaction with current labels. Certainly the hundreds of unsolicited letters sent to FDA document a real problem.

In a letter to the National Consumers League dated June 17, 1991, the Visiting Nurse Association (VNA) indicates their organization's concerns and recommendations "that FDA establish federal regulatory standards for print size and style of nonprescription OTC labels that are larger and easier to read." The letter notes that the VNA "provides care to patients in their homes including teaching proper medication regimes...which is difficult because of the patient's inability to read the labels on the bottles."

2. Should there be a mandatory minimum print size or other readability standard and, if so, what should it be? If the answer is yes, should this be established via a regulation or a guideline?

The League supports a **mandatory** minimum print size, but does not believe that sufficient studies and analysis are available to propose a minimum type size at this time. The League encourages the FDA to actively support independent research including consumer testing to establish a mandatory minimum type.

The League does not support **voluntary** programs or guidelines because frequently it results in minimal efforts by some manufacturers and nonparticipation by others and there is no penalty for noncompliance. For example, at the present time, NDMA has Voluntary Codes and Guidelines for the OTC Medicines Industry.

Among the eleven distinct areas in the voluntary program is the "Flag the Label" Guidelines to "aid in alerting consumers to significant changes in nonprescription medicines." ("Flag" is a term used by industry to designate an attention-getting label signal which alerts consumers to read the label carefully because of significant new information.) Unfortunately these guidelines are not being used by all manufacturers when the FDA requires new information to be added to the label.

3. Should a package insert or larger carton be mandatory if a minimum print size standard is implemented, and because of package size, the manufacturer is unable to meet the specifications?

The League encourages the FDA to explore several options before proposing regulations requiring a package insert or larger carton as a way to provide more space on the labeling if a minimum print size is implemented. Research is currently being done on some of the factors that FDA should take into consideration.

One alternative to a larger carton might be to increase the label surface area. Using consumers to evaluate different ways of increasing the label surface area on very small products, Barlow and Wogalter identified several viable methods to enhance product information and warning communication[2].

An alternative might be to develop regulations that specify exactly where on the labeling the information should be required. The present regulati[illegible] only indicat[illegible] that information from the

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[2]Barlow, Todd, and Wogalter, Michael S.,"Increasing the Surface Area on Small Product Containers to Facilitate Communication of Label Information and Warnings," Interface '91, Human Factors.

monograph should appear on the labeling without specifying whether it is required on the label of the bottle or on the package insert and/or the carton. The present regulations do have some minimal standards, for example: placement of product name and statement of identity on the bottle label. However, the manufacturer has some discretion in deciding where to put some information. For example, warnings can appear on the package insert or the back of the bottle. A 1986 study by Hadden reported by Bettman, Payne and Staelin[3] recommends putting particular types of information in the same place on all labels to help consumers quickly locate information.

The real value and use of package inserts should be examined closely. As Bettman, Payne, and Staelin note, "Package inserts can be used to provide detailed information at the point of usage. Since the insert is not as constrained by space limitations as the package label, more detailed information can be given. However, since the insert can become lost, particularly for products which are used multiple times, we feel that the label must have the major burden for communicating essential usage instructions."[4]

Another area to explore is the option of using the relatively large amount of space on OTC bottle labels currently used for the expiration date and the bar codes. Perhaps a different priority

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[3]Bettman, James R., Payne, John W. and Staelin, Richard, "Cognitive Considerations in Designing Effective Labels for Presenting Risk Information," Journal of Public Policy & Marketing, Volume 5, Division of Research, Graduate School of Business Administration, the University of Michigan, Ann Arbor, Michigan, 1986, p. 21.

[4]Id., p. 26.

should be set for using this valuable space.

5. What relevant data are available and what studies have been performed to determine optimum print size, background, contrast, etc. for package products?

The Canadian Coalition on Medication Use and the Elderly has a task force on packaging and labeling.[5] The Task Force #2 - Areas of Concern for Pharmacy - is reviewing the special needs of seniors in the packaging and labeling of medicines. Additional research is being done by Dr. Hugh Lockhart, Professor, Michigan State School of Packaging, East Lansing, Michigan 48824-1223 and Dr. Michael S. Wogalter, Assistant Professor, Rensselaer Department of Psychology, Rensselaer Polytechnic Institute, Troy, New York 12180-3590.

7. Will the NDMA guidelines be effective and have a positive impact on labeling and, if so, are these guidelines adequate so that a Federal regulation or guideline is not needed?

The League does not find the NDMA guidelines adequate to insure legibility or readability of OTC labels. On June 27, 1991, the League conducted an investigative survey of consumers in the Washington, DC area and found that 52 percent of the public is not able to read the minimum type size recommended by NDMA. The report of this investigation is attached.

The League is aware of the ongoing activities of the NDMA

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[5]Canadian Coalition on Medication Use and the Elderly, 1565 Carling, Suite 400, Ottawa, Ontario, Canada K1Z 8R1.

including the Special Task Force on Label Readability and the California Label Readability Group. These efforts have identified some of the basic considerations in developing readability of OTC labels. However, these groups have not tested consumers' ability to read various label combinations. These guidelines do not make specific recommendations and are sufficiently vague (with the exception of minimum type size which has already been addressed) to reinforce concern that the goals of readability and legibility of OTC labels will not be reached using these guidelines.

These NDMA guidelines have been approved by the NDMA Board of Directors and membership. NDMA is encouraging their membership to adopt these guidelines and start to implement the necessary labeling changes which presumably includes use of the minimum type size. This recommendation does not mention that the FDA is reviewing the need for guidelines or regulations for OTC labels.

The League encourages the FDA to move quickly and advise manufacturers of OTC products that the FDA will be issuing proposed regulations on type size and style of OTC labels. Of particular concern is the economic impact on the manufacturers who might incur additional labeling expenses twice: once using the NDMA guidelines and second the FDA regulations.

A

NATIONAL CONSUMERS LEAGUE

INVESTIGATION OF

CONSUMERS' ABILITY TO READ OTC LABELS WITH DIFFERENT TYPE SIZES

August 5, 1991

INTRODUCTION

The information provided on the labels of over-the-counter (OTC) medications is vital to the health and safety of millions of American consumers. The importance of the label is emphasized in the U.S. Food, Drug & Cosmetic Act, which defines nonprescription OTC medications as drugs that are safe to use without the intervention of a physician if the label instructions and warnings are followed. Yet the present FDA regulations on labels [Section 502(c), Federal Food, Drug & Cosmetic Act, 21 USC 352 (c)] only require that label information be "prominently placed" with "such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." The existing regulations do not specify print size or style that is to be used. No standards have been set to assure that the labels can be read.

On March 6, 1991, the FDA requested public comments on the need for regulatory standards for the print (optimum size and style) of OTC drug product labeling in order to maximize readability and legibility for persons with impaired or

deteriorating vision. Specifically, the FDA asked, "Will the Nonprescription Drug Manufacturing Association (NDMA) Guidelines be effective and have a positive impact on labeling and, if so, are these guidelines adequate so that a Federal regulation or guideline is not needed?"

The NDMA, the trade association of nonprescription drug manufacturers, has recently produced a set of voluntary guidelines for manufacturers on label readability. The NDMA guidelines suggest type size at least 4.5 points if dark-on-light type, and at least 6 points if reverse (light-on-dark) type. Other specifications which attempt to optimize label readability concern color, contrast, style, and spacing.

In order to evaluate the NDMA guidelines for readability, the National Consumers League on June 27, 1991, conducted an investigative survey to measure the ability of consumers to read actual product labels of several popular OTCs which were chosen based on the NDMA type size guidelines. Two labels were shown at 4.0 type size, two labels with 4.5, one label with 5.0, two labels with 6.0 of which one label of 6.0 is reverse type (the minimum NDMA guideline for reverse type), and one label with 6.5 type size. The sample for the survey was sixty randomly selected consumers; 37 women and 23 men with ages of 20 and over.

Although the design of the study only makes it possible to draw definitive results on readability based on type size of a few sample labels, the League believes these results indicate that type size is the most important element in investigating factors that influence label readability. The League recognizes that in addition to type size, variables such as type style, color, and contrast are also important in overall readability and can make a difference in legibility. Accordingly, the results of this investigation do present some tentative secondary conclusions regarding color and contrast.

II. EXECUTIVE SUMMARY AND RECOMMENDATIONS

The National Consumers League's investigative survey of consumers' ability to read OTC labels printed with the minimum type sizes recommended by the NDMA guidelines documents that a significant proportion of the adult population over 20 years in age is not able to read these labels. The League tested consumers' ability to read 4.5 pts type size with two labels and tested consumers with one label using the 6.0 pts type size recommended by NDMA when a reverse type is used.

The results of the League survey show that only 48 percent of the public, who currently purchases OTC medications, is able to read OTC labels with the 4.5 pts minimum type size recommended by the NDMA. Not surprisingly, people over 51 years of age have the most trouble reading the 4.5 pts with only 32 percent able to read the two tested 4.5 pts type size labels. However, the results for people under 51 are equally startling. Only 63 percent of these people are able to read the two labels with 4.5 type size.

The investigative survey also revealed that 80 percent of the public can read 6.0 reverse type size, the NDMA suggested minimum type size for white print on colored background. However, only 68 percent of the people over 51 were able to read the 6.0 reverse type size, with 91 percent of the population under 51 able to read the label.

The League recommends that the FDA not accept the NDMA guidelines on minimum type size until further research and testing of consumers' ability to read labels is completed.

III. MAJOR FINDINGS

The results of the NCL survey show that:

- Labels with type size 4.5 pts. could be read by **48%** of people*
- Label with type size 5.0 pts. could be read by **68%** of people
- Label with type size 6.0 pts could be read by **65%** of people
- Label with type size 6.5 pts. could be read by **85%** of people

The people over 51 years were most affected by the type size:

- **32%** of people 51+ could read labels with type size 4.5 pts.*
- **54%** of people 51+ could read a label with type size 5.0 pts.
- **50%** of people 51+ could read a label with type size 6.0 pts.
- **75%** of people 51+ could read a label with type size 6.5 pts.

People under 51 years were affected as well:

- **63%** of people under 51 could read labels with type size 4.5*
- **81%** of people under 51 could read a label with type size 5.0
- **78%** of people under 51 could read a label with type size 6.0
- **94%** of people under 51 could read a label with type size 6.5

* Combined survey results of Motrin carton and Tylenol carton

IV. DETAILED FINDINGS

o Only 57 percent of all the adults surveyed could read the Anacin carton with 4.5 pts type size, and fewer (40%) of the subjects were able to read the Tylenol label. The combined results for the two labels are 48 percent.

ABLE TO READ LABELS WITH TYPE SIZE 4.5 pts.

	of total 60 subjects	% of total
Anacin carton	34	57
Tylenol carton	24	40
Combined Total	**58/120**	**48**

o Not surprisingly, people over 51 had the greatest trouble reading labels of all type sizes.

TABLE OF PERCENTAGES FOR THOSE SUBJECTS 51 AND OVER

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
ANACIN bottle(4)	-	39%	61%	100%
MOTRIN bottle(4)	29%	50%	21%	71%
ANACIN carton(4.5)	39%	32%	29%	61%
TYLENOL carton(4.5)	25%	43%	32%	75%
MOTRIN carton(5)	54%	28%	18%	46%
TYLENOL bottle(6)	50%	32%	18%	50%
ADVIL bottle(6.5)	75%	21%	4%	25%

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o Even the people under 51 had trouble reading some labels.

TABLE OF PERCENTAGES FOR SUBJECTS BETWEEN THE AGES OF 20 AND 50

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
ANACIN bottle(4)	25%	44%	31%	75%
MOTRIN bottle(4)	63%	31%	6%	38%
ANACIN carton(4.5)	72%	28%	-	28%
TYLENOL carton(4.5)	53%	44%	3%	47%
MOTRIN car[illegible]5)	81%	16%	3%	19%
TYLENOL bottle(6)	78%	22%	-	22%
ADVIL bottle(6.5)	94%	6%	-	6%

o Only 68 percent of the people surveyed over 51 were able to read a label with reverse 6 point type, the suggested NDMA type size for reverse type. Ninety-one percent of the people under 51 were able to

read the label. Eighty percent of the total population was able to read the label.

ABLE TO READ REVERSE 6.0 TYPE SIZE LABEL

	(1) could read	(2) too hard to read	(3) couldn't see	couldn't read (2 + 3)
AGE:				
20-50	91%	9%	0%	9%
51+	68%	25%	7%	32%
Total	80%	17%	3%	20%

V. SUGGESTIVE FINDINGS ON COLOR CONTRAST

Although the L ue study was not designed to draw specific conclusions about ow certain color combinations affect readability, the results did suggest certain things:

o Despite the fact that both the Anacin and Motrin bottles

had a type size of 4 points, the Motrin bottle was much easier to read. Only 13 percent could read the Anacin green-on-yellow color combination. In contrast, 47 percent could read the Motrin black-on-white combination. Apparently black-on-white is easier to read than green-on-yellow.

- The Anacin carton and the Tylenol carton both had a type size of 4.5 points, but only 40 percent of the subjects could read the Tylenol label while 57 percent could read the Anacin label.This would suggest that Tylenol's black-on-red color combination is more difficult to read than Anacin's green-on-yellow.

- The Advil carton and the Tylenol bottle both had 6.0 type size. The Advil carton type was a reverse with white print on a blue background while the Tylenol bottle had black ink on red background. The survey results showed that 80 percent of the subjects could read the Advil carton with the reverse type, while only 65 percent could read the black on red type.

These tentative conclusions suggest that color combinations clearly have some impact on legibility, although not to the same degree as type size.

NATIONAL CONSUMERS LEAGUE SURVEY ON OTC LABEL READABILITY- SUMMARY

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
ANACIN (50 caplets)				
Carton (4.5)	34/57%	18/30%	8/13%	26/43%
Bottle (3)	8/13%	25/42%	27/45%	52/87%
MOTRIN (24 caplets)				
Carton (5)	41/68%	13/22%	6/10%	19/32%
Bottle (4)	28/47%	24/40%	8/13%	32/53%
ADVIL (100 tablets)				
Carton (6)	48/80%	10/17%	2/3%	12/20%
Bottle (6.5)	51/85%	8/13%	1/2%	9/15%
TYLENOL (60 tablets)				
Carton (4.5)	24/40%	26/43%	10/17%	36/60%
Bottle (6)	39/65%	16/27%	5/8%	21/35%

EDUCATION LEVEL LAST COMPLETED:

Grade school.....3/5%

High school.....3/5%

Professional School.....2/3%

some college.....13/22%

College Graduate.....25/42%

some schooling beyond college.....4/7%

Graduate School degree or more.....10/17%

AGE:

20-30.....14/23%

31-40.....6/10%

41-50.....12/20%

51+.....28/47%

Total over 40.....40/67%

SEX:

Female.....37/62%

Male.....23/38%

ANACIN bottle

TYPE SIZE: 4

COLORING: green on yellow

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**15%**	**42%**	**45%**	**87%**
AGE:				
20-30	5/36%	7/50%	2/14%	9/64%
31-40	1/17%	4/67%	1/17%	5/83%
41-50	2/17%	3/27%	7/64%	10/83%
51+	0%	11/39%	17/61%	28/100%
SEX:				
female	11%	44%	45%	89%
male	19%	36%	45%	81%
EDUCATION: (last completed)				
Grade School	0%	0%	100%	100%
High School	0%	67%	33%	100%
Professional School	0%	0%	100%	100%
Some College	8%	38%	54%	92%
College graduate	21%	42%	[illegible]	79%
Schooling beyond college	25%	50%	25%	75%
Graduate School degree or more	9%	55%	36%	91%

MOTRIN bottle

TYPE SIZE: 4

COLORING: black on white

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**47%**	**40%**	**13%**	**53%**
AGE:				
20-30	12/86%	1/7%	1/7%	2/14%
31-40	5/83%	1/17%	0%	1/17%
41-50	3/25%	8/67%	1/8%	9/75%
51+	8/29%	14/50%	6/21%	20/71%
SEX:				
female	45%	35%	15%	55%
male	50%	41%	9%	50%
EDUCATION: (last completed)				
Grade School	0%	67%	33%	100%
High School	67%	33%	0%	33%
Professional School	0%	50%	50%	100%
Some College	38%	39%	23%	62%
College graduate	50%	42%	8%	50%
Schooling beyond college	50%	25%	25%	50%
Graduate School degree or more	64%	36%	0%	36%

ANACIN carton

TYPE SIZE: 4.5

COLORING: green on yellow

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**57%**	**30%**	**13%**	**43%**
AGE:				
20-30	12/86%	2/14%	0%	2/14%
31-40	5/83%	1/17%	0%	1/16%
41-50	6/50%	6/50%	0%	6/50%
51+	11/39%	9/32%	8/29%	17/61%
SEX:				
female	61%	26%	13%	39%
male	50%	36%	14%	50%
EDUCATION: (last completed)				
Grade School	0%	100%	0%	100%
High School	33%	67%	0%	67%
Professional School	0%	50%	50%	100%
Some College	54%	31%	15%	46%
College graduate	58%	29%	13%	42%
Schooling beyond college	75%	0%	25%	25%
Graduate School degree or more	73%	18%	9%	27%

TYLENOL carton

TYPE SIZE: 4.5

COLORING: black on red

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**40%**	**43%**	**17%**	**60%**
AGE:				
20-30	11/79%	3/21%	0%	3/21%
31-40	4/67%	1/17%	1/17%	2/34%
41-50	2/17%	10/83%	0%	10/83%
51+	7/25%	12/43%	9/32%	21/75%
SEX:				
female	39%	42%	19%	61%
male	41%	45%	14%	59%
EDUCATION: (last completed)				
Grade School	0%	67%	33%	100%
High School	67%	0%	33%	33%
Professional School	0%	50%	50%	100%
Some College	31%	38%	31%	69%
College graduate	50%	46%	4%	50%
Schooling beyond college	50%	25%	25%	50%
Graduate School degree or more	36%	55%	9%	64%

MOTRIN carton

TYPE SIZE: 5

COLORING: black on white

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**68%**	**22%**	**10%**	**32%**
AGE:				
20-30	12/86%	2/14%	0%	2/14%
31-40	5/83%	1/17%	0%	1/17%
41-50	9/75%	2/17%	1/8%	3/25%
51+	15/54%	8/28%	5/18%	13/46%
SEX:				
female	71%	18%	11%	29%
male	64%	27%	9%	36%
EDUCATION: (last completed)				
Grade School	33%	67%	0%	67%
High School	67%	0%	33%	33%
Professional School	0%	50%	50%	100%
Some College	54%	38%	8%	46%
College graduate	79%	13%	8%	21%
Schooling beyond college	75%	0%	25%	25%
Graduate School degree or more	82%	18%	0%	18%

TYLENOL bottle

TYPE SIZE: 6

COLORING: black on red

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**65%**	**27%**	**8%**	**35%**
AGE:				
20-30	13/93%	1/7%	0%	1/7%
31-40	4/67%	2/33%	0%	2/33%
41-50	8/67%	4/33%	0%	4/33%
51+	14/50%	13/32%	5/18%	14/50%
SEX:				
female	68%	19%	13%	32%
male	31%	69%	0%	69%
EDUCATION: (last completed)				
Grade School	0%	100%	0%	100%
High School	67%	33%	0%	33%
Professional School	25%	75%	0%	75%
Some College	64%	9%	27%	36%
College graduate	78%	18%	4%	22%
Schooling beyond college	75%	0%	25%	25%
Graduate School degree or more	67%	33%	0%	33%

ADVIL bottle

TYPE SIZE: 6.5

COLORING: blue on white

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**85%**	**13%**	**2%**	**15%**
AGE:				
20-30	13/93%	1/7%	0%	1/7%
31-40	6/100%	0%	0%	0%
41-50	11/92%	1/8%	0%	1/8%
51+	21/75%	6/21%	1/4%	8/25%
SEX:				
female	87%	10%	3%	13%
male	82%	18%	0%	18%
EDUCATION: (last completed)				
Grade School	50%	50%	0%	50%
High School	67%	33%	0%	33%
Professional School	50%	50%	0%	50%
Some College	77%	23%	0%	23%
College graduate	92%	8%	0%	8%
Schooling beyond college	75%	0%	25%	25%
Graduate School degree or more	100%	0%	0%	0%

ADVIL carton

TYPE SIZE: 6

COLORING: REVERSE - white on blue

	(1) could read	(2) too hard to read	(3) couldn't see	(2 + 3)
TOTAL:	**80%**	**17%**	**3%**	**20%**
AGE:				
20-30	14/100%	0%	0%	0%
31-40	6/100%	0%	0%	0%
41-50	9/75%	3/25%	0%	3/25%
51+	19/68%	7/25%	2/7%	9/32%
SEX:				
female	79%	16%	5%	21%
male	82%	18%	0%	18%
EDUCATION: (last completed)				
Grade School	67%	33%	0%	33%
High School	100%	0%	0%	100%
Professional School	50%	0%	50%	50%
Some College	69%	31%	0%	31%
College graduate	83%	17%	0%	17%
Schooling beyond college	75%	0%	25%	25%
Graduate School degree or more	91%	9%	0%	9%

VI. RESEARCH DESIGN

A. Sample

NCL surveyed 60 adults from the general U.S. population, 20 years of age and over. (See Appendix A for survey questionaire). Subjects were chosen from shoppers in OTC sections of two Washington, DC area grocery stores (21 in the first store and 27 in the second store) and a senior citizen lunch group of elderly people (12 people) who still purchased their own medications. Although the subjects were chosen at random in the above settings, the researchers made some selections based on the sex and age of the prospective subject, to include a representative sampling of adult men and women over 20 years. NCL interviewed 37 women and 23 men.

A light meter reading was taken at each site to ensure that in all cases the subjects were reading labels under adequate light. In order to screen out potential subjects with severe vision problems, each subject was given an informal eyesight test using an acuity card to determine ability to see and each subject was allowed to move each label to whatever distance from the subject's eyes was most comfortable in order to read the label.

B. L

Eight labels were chosen for the survey: four carton labels and four labels on bottles. (See Appendix B for complete description) The point size for the specific lines on each of the

labels shown was verified by Dr. Hugh Lockhart, Professor, School of Packaging, Michigan State University. Manufacturers were also contacted for verification of type size. In two instances, the manufacturers reported type size other than Dr. Lockhart's analysis. (See Appendix C for Dr. Lockhart's table of measurements.)

The decision to include each medicine was based on the type size on the carton label. Two carton labels were chosen having 4.5 type size. As a result, the survey included the accompanying labels on the bottles which turned out to be 4.0. These labels were tested even though they were less than the NDMA recommended type size, since consumers frequently throw away the carton and then rely on reading the bottle label for instructions and appropriate warnings.

One series was chosen with the green ink on yellow background; one series was chosen with black ink on red; one series of black ink on white; and one carton with reverse type with the accompanying bottle of blue ink on white to test the effect of the color on readability.

C. Methodology

Two researchers from the League measured the ability of the subjects to read 8 labels from 4 cartons and 4 bottles of OTC medications using the following steps:

1. At all three sites, the researchers used a General Electric Type [illegible] Lightmeter to measure the foot candles of light in the area where the subjects would be viewing cartons and labels.

2. Prospective subjects were asked by the researcher to participate in a three-minute survey on the type size of various nonprescription labels.

3. Subjects were asked to look at the Rosenbaum vision screener acuity card (Medi-Source, Inc.) and, from a comfortable distance, read aloud the numbers on the line that was easily visible. The subject's responses and distance from the eye to the chart were recorded.

4. The subject was then given, one at a time, four cards with labels and four bottles, and was asked to read aloud specific lines on each label. The subject was allowed to move the card or bottle to a distance from his/her eyes that was comfortable to read. Again the subject's responses and measured distance from the eye to the material were recorded.

Subjects ability to read the information on each label was recorded using three different categories: One possible response was "read" indicating that the person read the lines easily. The "can't see" response indicated that the subject could not read any of the words on the label. The "too hard" response was used when the subject started to read the words and gave up, indicating that it was possible but too frustrating to continue to read. This third category was recorded because the result is the same as not being able to see the words on the label: The consumer does not read the label warnings and directions.

All subjects were asked to read the eight samples in the same order and from the same point on the printed materials:

a. Anacin carton - from "WARNING..." to "...product."
   Anacin bottle - from "CAUTION..." to "...immediately."

b. Motrin IB carton - from "MOTRIN IB..." to "...it."
   (in middle of text where Motrin appears in bold)
   Motrin IB bottle - from "WARNING..." to "...aspirin."

c. Advil carton - from "WARNING..." to "...aspirin."
   Advil bottle - from "DIRECTIONS..." to "...doctor."

d. Tylenol carton - from "WARNING..." to "...PHYSICIAN."
   Tylenol bottle - from "Severe..." to "...physician."

5. The subject was then asked to indicate his/her age and education level according to the categories on the response sheet.

SPECIAL ACKNOWLGEMENTS

The League would like to thank Dr. Hugh E. Lockhart Professor, School of Packaging, Michigan State University School and Associate Director for Center for Food and Pharmaceutical Packaging Research, for his suggestions in the design of the survey. In addition to providing verification of the type size on the surveyed labels, Dr. Lockhart recommended a light meter to measure footcandles and an acuity card to screen applicants' ability to read. To facilitate Dr. Lockhart's research efforts on label readability, the League gathered data on the distance from the eye to label used by each subject, measured the footcandles of light and used his recommended age breakdown and educational level on the questionnaire.

The League also appreciates the efforts of Odonna Matthews, Vice President Consumer Affairs at Giant Food Stores, Inc., for making arrangements for the survey to be conducted in stores in Bethesda, Maryland and Falls Church, Virginia. Paula Hoffman, Coordinator of the SuperSixties Program of Iona House in Washington DC, graciously allowed her senior citizens to be part of the survey. Kay Layne at Daniel, Mann, Johnson and Menhenhall architectual firm supplied the lightmeter.

The survey was directed by Mary Ponder, Deputy Director of the League. Program Associate, Daniel Helfman assisted in research and conducting the survey, Allison Rooney interpreted the data and wrote the final report. Gala Dechavanne verified the survey results.

APPENDIX A

NATIONAL CONSUMERS LEAGUE SURVEY ON OTC LABEL READILITY

Eyesight_____

Footcandles of light_____

Other Comments:

---

	read[1]	too hard[2]	can't see[3]	distance[4]
Anacin, 50 Caplets				
Carton(4.5)_____				
Bottle (4)_____				
Motrin IB, 24 caplets				
Carton(5)_____				
Bottle(4)_____				
Advil, 100 tablets				
Carton(6)_____				
Bottle(6.5)_____				
Tylenol, 60 tablets				
Carton(4.5)_____				
Bottle(5)_____				

---

ducation Level (check one):

Last grade completed_____ Completed High School_____ Attended rofessional School_____ Some College_____ College Graduate_____ Some chooling beyond college_____ Graduate School degree or more_____.

ge (circle one):

20-30 31-40 41-50 51 +

Sex (circle one):

Female Male

Site_____ Subject No._____

---

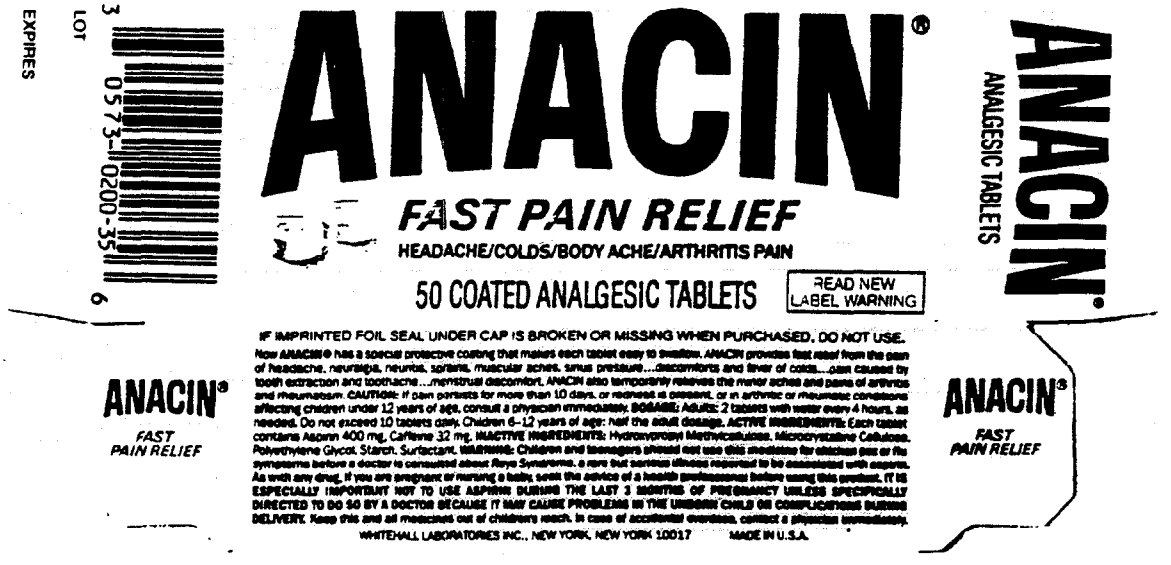
[1] Subject read three lines

[2] Subject found type "too hard" to want read

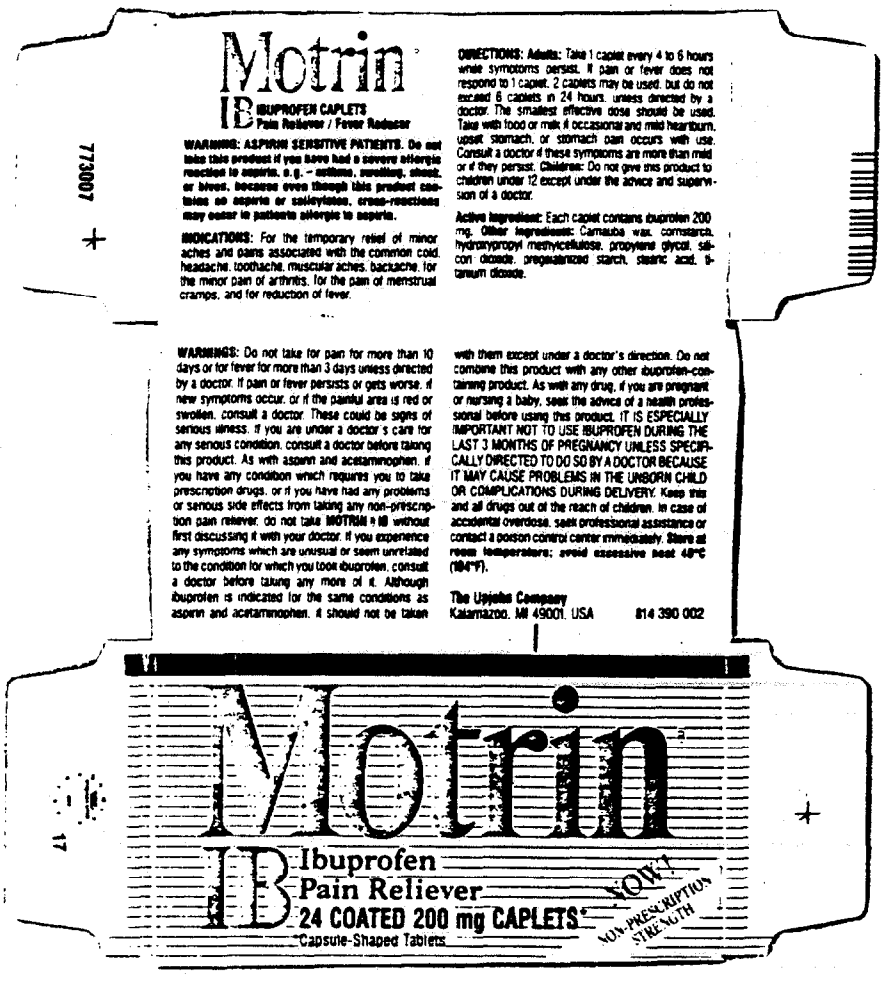
[3] Subject could not see the words

[4] Product first at 13" - subject allowed to find comfortable distance

APPENDIX B



Whitehall Laboratories
American Home Products Corporation



Motrin
IB IBUPROFEN CAPLETS
Pain Reliever / Fever Reducer

773007

WARNING: ASPIRIN SENSITIVE PATIENTS. Do not take this product if you have had a severe allergic reaction to aspirin, e.g. – asthma, swelling, shock, or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin.

INDICATIONS: For the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps, and for reduction of fever.

DIRECTIONS: Adults: Take 1 caplet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 caplet, 2 caplets may be used, but do not exceed 6 caplets in 24 hours, unless directed by a doctor. The smallest effective dose should be used. Take with food or milk if occasional and mild heartburn, upset stomach, or stomach pain occurs with use. Consult a doctor if these symptoms are more than mild or if they persist. **Children:** Do not give this product to children under 12 except under the advice and supervision of a doctor.

Active Ingredient: Each caplet contains ibuprofen 200 mg. **Other Ingredients:** Carnauba wax, cornstarch, hydroxypropyl methylcellulose, propylene glycol, silicon dioxide, pregelatinized starch, stearic acid, titanium dioxide.

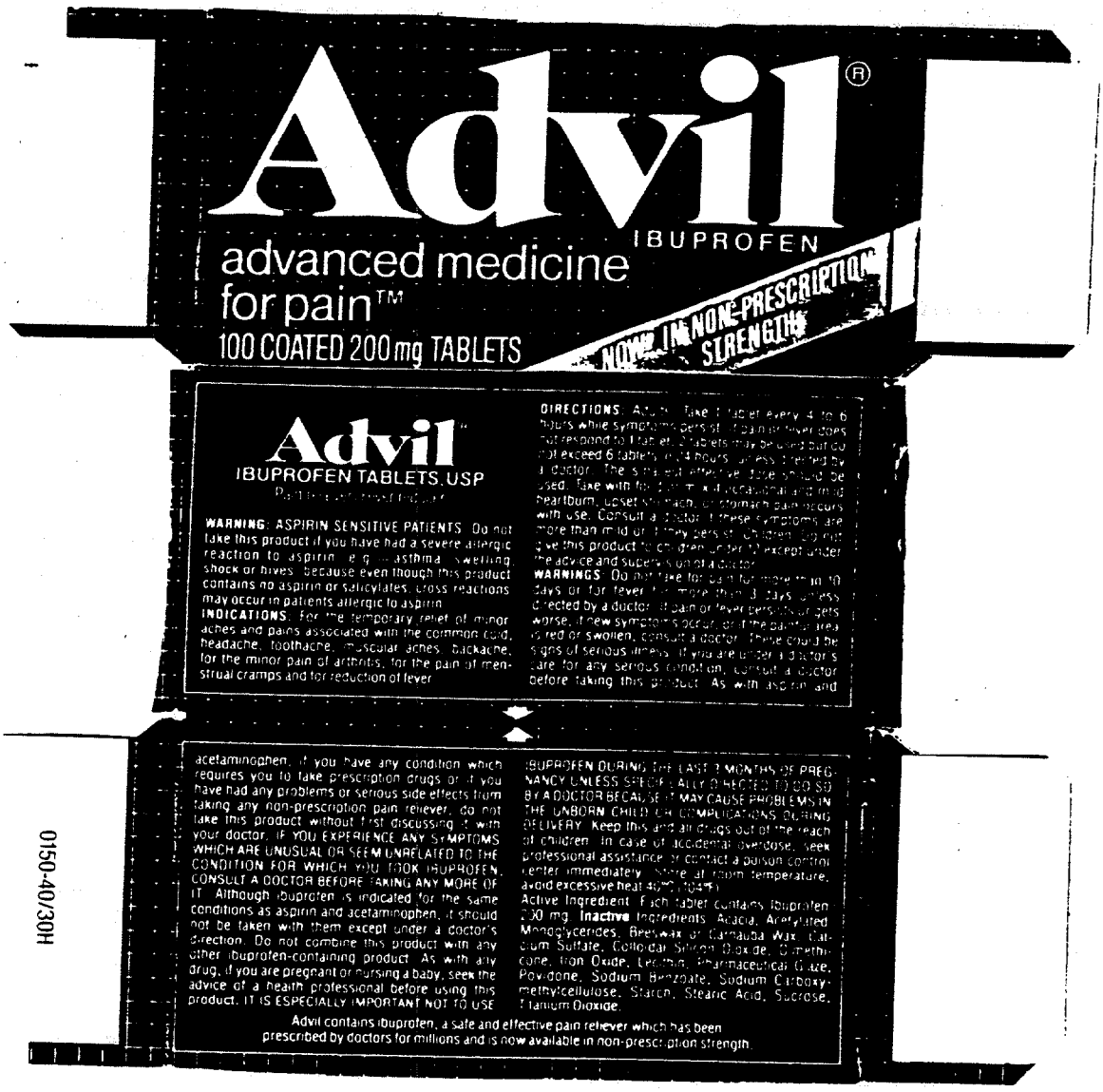
WARNINGS: Do not take for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if the painful area is red or swollen, consult a doctor. These could be signs of serious illness. If you are under a doctor's care for any serious condition, consult a doctor before taking this product. As with aspirin and acetaminophen, if you have any condition which requires you to take prescription drugs, or if you have had any problems or serious side effects from taking any non-prescription pain reliever, do not take MOTRIN IB without first discussing it with your doctor. If you experience any symptoms which are unusual or seem unrelated to the condition for which you took ibuprofen, consult a doctor before taking any more of it. Although ibuprofen is indicated for the same conditions as aspirin and acetaminophen, it should not be taken with them except under a doctor's direction. Do not combine this product with any other ibuprofen-containing product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Store at room temperature; avoid excessive heat 40°C (104°F).

The Upjohn Company
Kalamazoo, MI 49001, USA 814 390 002

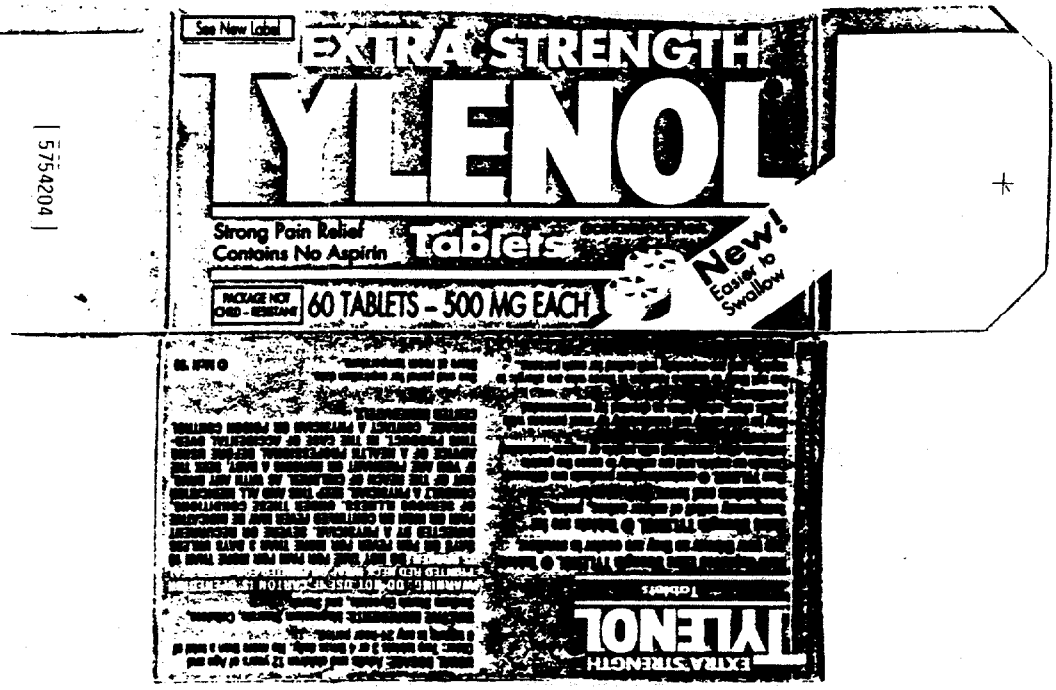
17

Motrin
IB Ibuprofen
Pain Reliever
24 COATED 200 mg CAPLETS*
Capsule-Shaped Tablets
NOW NON-PRESCRIPTION STRENGTH

The Upjohn Company



Whitehall Laboratories
American Home Products Corporation



McNeil Consumer Products

APPENDIX C

SCHOOL OF PACKAGING

TABLE OF TYPE SIZE MEASUREMENTS
FOR LABEL LEGIBILITY PACKAGES
TESTED BY
NATIONAL CONSUMERS' LEAGUE

Product	Package	Total Letter Height Inches	mm	Height in Points	Point Size
MOTRIN	Carton	0.061	1.5	4.4	5
	Bottle	0.052	1.3	3.7	4
ANACIN	Carton	0.058	1.5	4.2	4.5
	Bottle	0.040	1.0	2.9	4
TYLENOL	Carton	0.062	1.6	4.5	4.5
	Bottle	0.081	2.1	5.8	5
ADVIL	Carton	0.075	1.9	5.4	6
	Bottle	0.084	2.1	6.1	6.5

Total letter height is measured from the bottom of a descender (such as the tail on a "y" or the bottom loop of a "g") to the top of an ascender (such as the top of a "d" or the top of the letter "l".

Height in points is the conversion of total letter height in inches to the point measure used by printers. The factor is, 1/72 inch = 1 point.

Point Size is the nominal size as given by the packager of the product. The difference between nominal and calculated size is not surprising. Most of the time, actual size of type will be a little smaller than the stated size.

Our measurements indicate there may be two errors in the information given by manufacturers. The Anacin bottle label must surely be 3 point type, not 4, and the Tylenol bottle label must 6 point type, not 5.

When we do our analysis, we will do calculations based on our measurements of letter height. We intend to use visual angle for comparison with the work quoted by NDMA.

SCHOOL OF PACKAGING

SUPPLEMENTARY REPORT
TYPE SIZE OF LABELING ON PACKAGES
TESTED FOR LEGIBILITY BY
NATIONAL CONSUMERS LEAGUE

We measured again the type size on the carton and bottle label for Anacin 50 tablet size, and we measured also type size on the carton and bottle label for Anacin 30 tablet size. The results are tabulated below:

Product	Package	Total Letter Height Inches	mm	Height in Points	Point Size
ANACIN 50	Carton	0.0591	1.5	4.3	4.5
	Bottle	0.0423	1.1	3.0	4
ANACIN 30	Carton	0.0554	1.4	4.0	?
	Bottle	0.0365	0.93	2.6	3

Total letter height is measured from the bottom of a descender (such as the tail on a "y" or the bottom loop of a "g") to the top of an ascender (such as the top of a "d" or the top of the letter "l").

Height in Points is the conversion of total letter height in inches tp the point measure used by printers. The factor is, 1/72 inch = 1 point.

Point Size is the nominal size as given by the packager of the product. The difference between nominal and calculated size is not surprising. Most of the time, actual size of type will be a little smaller than the stated size. We do not know what size the packager claims for the carton for the 30 tablet bottle.

These measurements still indicate a discrepancy between the measured size and the size given by the manufacturer. It seems that the discrepancy exists for the bottle label for both sizes, but not for the carton for either size.

We suggest that the bottle label copy is prepared in an enlarged version like 6 or 8 point, and ordered in 50% reduction for the [illegible]uction labels. Then, during the reduction process, the [illegible]al reduction is more than 50%.

NCLTYPE 8/1/91

EXHIBIT 11

Consumer Healthcare Products Association

Representing Producers of Quality Nonprescription Medicines and Dietary Supplements

Founded 1881

Sharing Industry's Concerns on the Final OTC Label Rule:

Column Format & Other Matters

[Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

William W. Bradley
Vice President ~ Technical Affairs

Outline

- Introduction
  - Needed Outcomes Today
  - Overview: Areas of Concern
- Specific Comments on Column Format
- Discussion

Needed Outcomes Today

1 Frank and open dialogue

2 Positive feedback on the use of columns

3 Assurance that there is a timely and efficient process to handle possible letters for exemption

4 Discussion an extension of the implementation date to account for our understanding of, and our dialogue on, this complex rule

5 Agreement on additional meetings

Overview: Areas of Concern

- This is the most comprehensive and complex OTC final rule, affecting more products, and more SKU's at one time, than any other.
  - Tremendous resource burdens: Regulatory Departments, Legal Departments, Art Departments, Package Engineering, Manufacturing Plant, Store Brand Retailer and Vendors … and potentially FDA.
  - Significant capacity issues
  - Product returns
  - International registration (CPP)
  - Web site changes

***Current status:* industry is test driving the Final Rule as to how it *actually* fits the marketplace.**

Where and How to Fit All the Required Information

- **Available Printable Space:**
  - UPC symbol
  - Other Required Information:
    - Name/Place of Manufacturer; Lot Number; Expiration Date; TRP Statement(s); Non-USP Disclaimer; State labeling requirements
  - Physical packaging constraints
    - E.g., seams, shrink wraps, no varnish areas
  - Content issues: manipulation of other Final Rule wording
  - Convenience sizes and small packages
- **Columns & the Exemption Process**

Where and How to Fit All the Required Information

Other Required Information

- **Per CFR**
  - Name and place of business of the manufacturer, packer or distributor (21 CFR 201.1)
  - Expiration date (21 CFR 211.37)
  - Lot number (21 CFR 201.18)
  - TRP statement (21 CFR 211.132)
  - "Made in ..." for imported products (19 CFR 134.11)
- **Other Agency/Council Required Information**
  - UPC Symbol & Code
  - Non-USP disclaimer
  - Required FIFRA labeling (EPA registration, establishment number, other labeling)
  - Recycle seal (state mandated)
- **Other Legal Requirements**
  - Patent number
  - Copyright
  - Trademark disclosure for unique constituents (e.g., aspartame/ NutraSweet®)
  - Court-mandated store brand comparison statements & disclaimers (with line for registered trade-mark of other company's product)
  - Voluntary warnings and statements
- **Other Important Consumer Information**
  - Medical and Professional Society Endorsements
  - Customer guarantees

Where and How to Fit All the Required Information

The Exemption Process is Important!

- 100,000 OTC SKU's (FDA's estimate)
- ~ 92% of SKU's will fit (FDA/ERG's estimate)
- 8.1% (8,100 SKU's) will not fit, need reconfiguring (FDA's estimate)
  - Our preliminary Final Rule estimates indicate 8.1% is very low.

- ***If FDA were to receive 8,100 letters for exemption,***
  ...it would take two FTE's
  ...at only 30 min/letter*
  ...289 work days (i.e., 57 weeks) to process these requests

* Even if not "routinely granted," the exemptions would need to be reviewed expeditiously and acted on if the exemption process is to meaningful.

Re: Exemptions

- Reasons not many requests for exemption to date:
  - Industry's uncertainty re: use of columns;
  - Industry's uncertainty re: the exemption process

The answer to these questions will determine, in large part, the number of exemption requests that will have to be filed.

Note also:

- The Final Rule
  - Is a fit for a large ***majority*** of OTC labels;
  - Will likely not fit a large ***number*** of OTC labels (~30% of SKUs);
- The delay in coming to a determination on columns cuts into the implementation time for a large *number* of OTC labels.

As a result, a discussion is needed on how to fairly accommodate those packages affected by this delay in terms of an extension of the implementation date.

Outline

- Introduction
  - Needed Outcomes Today
  - Overview: Areas of Concern

➡ Specific Comments on Column Format

- Discussion

Introduction on Columns

- All factors that affect readability work in concert.
  - Both columns and white space enhance readability.
  - No data to suggest that white space is more important than use of columns or *v.v.*
    - No data to suggest "a lot" white space is better than some white space to make text appearance more "friendly."
    - Generally accepted that lines much longer than 39 characters decrease readability in proportion to their increasing lengt[illegible]
- In any case, it is not a matter of which is better – white space or columns; both are preferred, ***if achievable***.

Introduction on Columns

- We know: Columns can be used with the new format:
  - To efficiently use label space
  - While still allowing greater white space than previously used routinely on OTC labels.

- On balance: the ability to use columns would likely:
  - Have no negative impact on OTC label readability;
  - Enhance label readability.

William W. Bradley
Vice President ~ Technical Affairs

- Columns
  - The effective utilization of label space.
  - The use of columns to increase readability.

Discussion Points

1 Feedback today on the use of columns.

2 Explanation of the operational status of the exemption process.

3 Discussion an extension of the implementation date to account for the time spent in industry's understanding of, and the FDA/industry dialogue on, this complex rule.

4 Agreement on additional meetings.